



Case studies on access and benefit-sharing

*Compiled and edited by
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This collection of country case studies were commissioned as inputs into a project executed by the International Plant Genetic Resources Institute (IPGRI) entitled *Access and plant genetic resources for food and agriculture: Exploring options to implement the International Treaty on Plant Genetic Resources for Food and Agriculture and Article 15.2 of the Convention on Biological Diversity* (the project). The case studies address access and benefit-sharing laws and law making initiatives in Costa Rica, El Salvador, Ghana, Guatemala, Malawi, Nicaragua, Nigeria, Panama, South Africa and Uganda.

The overall object of the project was to develop a tool to assist policy-makers and advocates “think through” their options concerning access and benefit sharing laws. The tool that was eventually produced is included in a companion volume, entitled *Methodology for Developing Policies and Laws for Access to Genetic Resources and Benefit Sharing*.

The final stage in the development of this tool was a two-week series of meetings with a wide range of stakeholders from the Seychelles, during which the basic steps identified in the methodology were tested and refined. The draft national ABS law developed in the course of those meetings is included in a second companion volume, entitled *Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill* (2005).

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Acronyms used in the text

ABS	Access and Benefit-Sharing
CBD	Convention on Biological Diversity
CCAD	Central American Commission of Environment and Development
CGIAR	Consultative Group on International Agricultural Research
CITES	Convention on International Trade in Endangered Species of Wild Flora and Fauna
CONADIBIO	National Coordinator for Biological Diversity, Guatemala
CONAGEBIO	National Commission for the Management of Biodiversity, Costa Rica
CONAMA	National Commission for the Environment, Guatemala
CONAP	National Council for Protected Areas, Guatemala
CONARFI	National Commission for Plant Genetic Resources, Guatemala
CSIR	Council for Scientific and Industrial Research
CSRPM	Centre for Scientific Research into Plant Medicine, Ghana
DEAT	Department of Environmental Affairs and Tourism, South Africa
DENR	Department of Environment and Natural Resources, El Salvador
EIA	Environmental Impact Assessment
FAO	Food and Agriculture Organization of the United Nations
GRPI	Genetic Resources Policy Initiative
ICBG	International Cooperative Biodiversity Group
ICTA	Institute of Science and Agriculture Technology, Guatemala
ILO	International Labour Organization
INAB	National Forest Institute, Guatemala
INBio	Instituto Nacional de Biodiversidad (Costa Rica)
INCOPESCA	Costa Rican Institute of Fishing and Aquaculture
IPGRI	International Plant Genetic Resources Institute
IPGRI	International Plant Genetic Resources Institute
IPR	intellectual property right
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN-ELC	Environmental Law Centre of the International Conservation Union
LEG	Legal Expert Group
MAG	Ministry of Agriculture and Livestock, Costa Rica
MAGA	Ministry for Agriculture, Livestock and Feed, Guatemala
MAGFOR	Ministry of Agriculture and Forestry, Nicaragua
MARENA	Ministry of the Environment and Natural Resources, Nicaragua
MAT	mutually agreed terms
MENR	Ministry of Environment and Natural Resources, El Salvador
MES	Ministry of Environment and Science, Ghana
MIFIC	Ministry of Promotion, Industry and Trade, Nicaragua
MTA	material transfer agreement
NARO	National Agricultural Research Organization, Uganda
NBI	National Botanical Institute – now SANBI <i>q.v.</i>
NBSAP	National Biodiversity Strategy and Action Plan
NEMA	National Environmental Management Authority, Uganda
NEMA	National Environmental Management Act, South Africa
NGO	Non-governmental organization
PBR	Plant Breeders' Rights
PGRC	Plant Genetic Resources Centre, Bunso, Ghana
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	prior informed consent
PRONAREGE	National Programme for Genetic Resources, Guatemala
SADC	Southern African Development Community
SANBI	South African Biodiversity Institute
SEAPRI-ICIPE	Southern Environmental and Agricultural Policy Research Institute of the International Centre of Insect Physiology and Ecology
SINAC	Directorate of Wildlife of the National System of Conservation Areas, Costa Rica
SPDA	Peruvian Society for Environmental Law
TK	Traditional Knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCST	Uganda National Council for Science and Technology
USAID	United States Agency for International Development

Introduction

Intergovernmental discussions with a real or potential impact on the exchange of plant genetic resources and the sharing of benefits arising from the use of these resources are taking place in multiple forums. Nationally, interests in, and responsibilities for, plant genetic resources tend to be fragmented among diverse ministries. Nevertheless, countries still have to be able to respond in a coherent way to requests for access and agreements to exchange genetic resources, so that both international obligations and national interests are accounted for.

Through research and workshops for exchanging experience, ideas and expertise, the goal of this project was to create a policy-making tool that helps policy-makers understand the key decision points in Access and Benefit-Sharing (ABS) policy development, and that emphasizes linkages between policy objectives and implementation approaches. The information gained aims to be useful for countries whether they are at the beginning stages of developing an ABS strategy, are considering regulations, or are assessing the effectiveness of their current regime.

While the Convention on Biological Diversity (CBD) provides the general legal framework within which mechanisms concerning ABS are to operate, the actual implementation is expected to be largely at the national level. The Convention has been ratified by most countries in the world, but very few have actually put in place the legal and policy mechanisms for its implementation. Furthermore, many countries have ratified or acceded to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or indicated their intention to do so, thereby accepting an obligation to develop an ABS regime that include specific provisions addressing plant genetic resources for food and agriculture (PGRFA). Even where countries do have some form of ABS regime in place, albeit *ad hoc* in many cases, implementation has been a major challenge and specific provisions for PGRFA are virtually absent.

In practice, multiple interests, sectors and actors are influenced by and hence have a stake in regimes that regulate ABS in genetic resources. Therefore, it was felt that understanding the key decision points in making an access decision and making available the critical (legal, scientific, technical, socio-economic, cultural, etc.) information needed at each of these points would help decision-makers in assessing the situation and coming to a decision that makes sense in the light of international obligations and also addresses national interests. This project entitled *Access and plant genetic resources for food and agriculture: Exploring options to implement the International Treaty on Plant Genetic Resources for Food and Agriculture and Article 15.2 of the Convention on Biological Diversity* ('the project') was formulated with the objective of creating a decision-making tool that would help decision-makers to understand the process, key decision points and the information required to achieve sound decisions in ABS. The basic hypothesis underlying the decision-making methodology is that with good information and a framework for sound analysis, decision-makers will be able to develop ABS policies and regulatory frameworks in the light of national needs and international obligations with more certainty and with less reliance on outside assistance than currently is the case.

Case studies on legal and policy frameworks for access to genetic resources and benefit sharing

A series of country studies were commissioned as background papers for the various workshops of the project. They have been used as sources of examples for the elaboration of the policy formulation methodology in the decision-making tool itself.

Regional workshops

The first subregional workshop as part of the project – for East, Central and West Africa – was held in December 2003. The workshop was hosted by the Ethiopian Agricultural Research Organisation (EARO). The objectives of the project were presented, and participants shared their experiences regarding the key decision points in ABS processes. At an early stage of the proceedings, workshop participants identified awareness creation; sovereignty and rights; benefit sharing; access; policy-making processes; and capacity building as major areas of concern in policy-making. The workshop then divided into working groups that focused on the steps and decision points in processing access requests and reaching a decision. These steps and decision points in handling access applications were discussed around three scenarios: a model case scenario, a real case scenario in Africa with legislation, and real cases in situations without legislation. A synthesis of the group discussions effectively identified seven key stages:

1. establishing contact between the applicant and a local counterpart;
2. dialogue between these parties on prior informed consent (PIC), mutually agreed terms (MAT), and the terms of a material transfer agreement (MTA);
3. agreement on the terms of a MTA incorporating aspects of PIC and MAT;
4. application of a request for export to the Competent National Authority;
5. assessment by the Competent National Authority of the application;
6. issuing a permit and the conditions; and
7. monitoring the implementation.

The conclusions of the Ethiopia workshop thus focused on the nature of the problems that countries were facing in the implementation of ABS strategies and regimes.

A second regional workshop was held, for Central American countries, in San Jose, Costa Rica, in January 2004. This workshop was hosted by the Instituto Nacional de Biodiversidad (INBio). The workshop began with the same approach as that in Ethiopia: i.e. an examination of the problems faced by countries in implementing ABS strategies and regimes. However, discussion by participants moved from consideration of these problems to the possible factors underlying them and, in particular, problems with the process of policy formulation in the context of ABS. Several of the workshop's conclusions highlighted this issue:

- the fact that ABS policy-making was usually based on a limited information base;
- the restrictive and complex ABS procedures developed in the mid-1990s tend to inhibit rather than further policy objectives such as the promotion of research;
- benefit sharing is often narrowly construed as focusing on financial benefits, and this tends to prejudice other benefit sharing approaches, such as capacity building through training, collaborative research and access to research results; and
- different categories of ABS-based activities, such as traditional plant breeding and modern pharmaceutical research, should be distinguished, and these distinctions should be reflected in the structure and characteristics of ABS policies and regimes.

The third regional workshop, for southern African countries, was held in Cape Town, South Africa, in May 2004. This workshop was hosted by the Department of Agriculture of South Africa. This workshop built upon thinking developed at the Costa Rica workshop and focused upon linking the objectives and implementation mechanisms of access to genetic resources and benefit-sharing (ABS) policies and regulatory regimes. The workshop opened with a series of presentations on country situations and experiences in ABS, followed by general discussion of these presentations and an exercise in identifying the main motivations for ABS regulations emerging from the presentations and the experiences of the participants.

These motivations were then carried through to form the foundation of the second phase of the workshop.

The second, and principal, phase of the South Africa workshop sought to consider key aspects of the country presentations through a basic hypothesis agreed upon by the Legal Expert Group that met to examine the results of the Costa Rica workshop (see below for further details on the Legal Expert Group). The basic hypothesis was that ABS regimes frequently lack coherence and are difficult to assess in terms of effectiveness due to weak or absent linkages between objectives and implementation. To address this situation, the outline of a possible decision-making tool that strongly emphasizes internal coherence in policies and legislative instruments was presented to, and tested by, workshop participants. The testing was undertaken through three working groups that considered individual possible objectives for the development of ABS regimes, and the policy and legal components and mechanisms that might form a basis for achieving these objectives.

The outcomes of the working groups highlighted the complexity of ABS policy-making. They also highlighted the need for further refinement of the tool, both in terms of its structure and, perhaps most importantly, in terms of its 'meta-narrative', i.e. the explanatory text that accompanies each step in the process. However, despite these shortcomings, the conclusion of the majority of participants appeared to be that the tool had the potential to usefully guide and focus policy development processes without predetermining, or imposing uniform, outcomes.

The fourth, and final, regional workshop, for Asian countries, was held in Chennai, India, in September 2004. The workshop was hosted by the M.S. Swaminathan Research Foundation. The workshop opened with short country presentations focusing on the objectives of ABS policies and regimes and moved quickly to work on a further refined decision-making tool in country-specific working groups. These working groups built upon the lessons learned from the South Africa workshop and the subsequent work of the Legal Expert Group. The working groups used the policy formulation elements of the draft tool to examine their national situations and, where applicable, existing ABS regimes, and then met in plenary to consider views on the draft tool and experiences. The workshop included participants from India, Malaysia, Nepal, Philippines and Viet Nam. With a greater density of participants from the same countries, they could be divided into country-specific small groups to focus on the particular circumstances of their own countries.

Legal expert group

The Legal Expert Group (LEG) – comprising up to seven experts in the field of ABS law and policy – provided the leadership for the development of the methodology.

As noted earlier, the first meeting of LEG was in San Jose, Costa Rica, following the workshop for Central American countries. From the deliberations of the workshop, LEG explored the hypothesis that the implementation of ABS regimes has been problematic due to inadequate linkages between implementing mechanisms and underlying policies. As a means of ameliorating this deficit in policy analysis, the group took the first steps in outlining a policy development methodology that focuses on the decision-making process rather than on models for regulatory regimes.

The participants at the South Africa workshop generally endorsed the concept underlying the outline methodology developed in Costa Rica. However, experiences in South Africa also highlighted serious shortcomings in the outline methodology, in particular specific weaknesses in certain steps and a general problem resulting from the absence of adequate descriptive text – a 'meta-narrative' – accompanying the methodology. Subsequently, LEG met and considered options for addressing the shortcomings highlighted during the workshop.

LEG met for a third time alongside a workshop of IPGRI's Genetic Resources Policy Initiative, in Ottawa, Canada, in June 2004. At this meeting the group began to address the shortcomings identified in South Africa. The result was a substantially revised outline of the methodology that, in particular, contained the basic elements of a meta-narrative. This LEG meeting closed by agreeing to begin developing the outline methodology into a 'user-friendly tool' for the development or analysis of ABS frameworks, in preparation for its next planned meeting, in Rome, before the regional workshop in Chennai.

At its fourth meeting, LEG considered a thoroughly revised and expanded draft tool. Relatively intense discussion over a period of three days focused on a number of key issues, including:

- The identification of a practical 'entry point' to the tool in the form of a basic motivation or 'political mandate'.
- Concern over the placing of decision-making elements within the structure of the tool to facilitate or promote maximum participation.
- The nature and placing of 'filters' to ensure the viability of and compatibility with ABS of proposed policy measures.
- The relative feasibility of sequential versus continuously interacting approaches in the implementation of the various steps of the tool.
- The openness of the tool to varying inputs from interest groups and sectors.
- The flexibility of the tool in allowing for varying outcomes and to avoid predetermination, and, thereby, an alternative means of promoting models.
- The need for a nested approach in presenting the tool and 'drawing users in' gradually, consisting of: an initial summary of no more than a few pages; a longer 'working version' of the tool; and a full reference version, including broad and in-depth reference material and links (the latter to be developed in the future according to the success of the tool and availability of resources).

Plans for work in Seychelles were finalized in early 2005, and the available members of LEG, with the addition of an FAO lawyer, acted as facilitators for stakeholder workshops and as the core of a drafting team. Several LEG members also provided valuable comments and suggestions in the finalization of project documents.

Developing draft legislation in Seychelles

The conclusions of the Asian regional workshop, and the work of LEG, strongly suggested the need for in-country work to place the decision-making methodology firmly in the context of the development of national legislation, as opposed to international debates regarding access to genetic resources. During the research phase of the project, the Government of Seychelles had clearly indicated its political will for the development of legislation on access to genetic resources that would address its concerns in both the agricultural and environmental sectors. This opportunity was taken to conclude the activities of the ABS project with a series of stakeholder workshops designed to support the work of LEG and local experts in the development of draft legislation, presented in a companion volume, entitled *Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill* (2005).

1. Central America: Costa Rica, Guatemala, El Salvador, Nicaragua and Panama¹

Manuel Ruiz Muller

Introduction

Central America is one of the few remaining megadiverse regions in the world. Its biological and genetic diversity has been extensively documented and is widely recognized. Biodiversity is a critical element in the region's potential economic and social development.

All Central American countries are Contracting Parties to the CBD. Most have developed general guiding policies on ABS, mainly through their National Biodiversity Strategies and Action Plans (NBSAPs) and a wide range of other instruments. Most countries in the region have not developed specific policies, laws and regulations regarding ABS. However, Costa Rica is a pioneer, with a long standing tradition in bioprospecting activities that can be traced to the early 1990s through the National Institute for Biodiversity (INBio). In most cases, there is a need for creating, clarifying or complementing institutional competences and jurisdiction with regards to genetic resources.

This does not imply that access to and use of biological resources (specimens, germplasm, genetic material and seeds) is unregulated. Collecting permits and authorizations have been traditional state administrative tools to enable the biological patrimony and wealth of the region to be evaluated, researched (classified), monitored and, ultimately, industrialized and commercialized, either within or outside the countries. Nevertheless, the availability of information regarding access applications, projects and status of specific administrative procedures is limited and has not been collated in an orderly manner. Existing documents and reports provide limited information on the specific policy and legal ABS context in each Central American country.

This non-exhaustive and summarized report seeks to present an overview of the policy and legal ABS situation in Costa Rica, El Salvador, Guatemala, Nicaragua and Panama.

A regional policy and framework for biodiversity and access to genetic resources

In 1992, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama signed the Convention for the Conservation of Biodiversity and the Protection of Wilderness Areas in Central America. This has been ratified by all Central America countries except Belize.

The key obligations under this biodiversity framework agreement are to:

- adopt measures to conserve, use and develop biodiversity within national jurisdictions and cooperate in regional actions;
- incorporate biodiversity valuation and use into development policies and plans;
- cooperate with regional and international institutions to realize the obligations under the convention, especially in areas of biotechnology, health and food security;
- cooperate with the Central American Commission for the Environment and Development (CCAD) to adopt measures to implement the Convention;
- implement legal and economic measures to use and develop biodiversity components;

¹ Belize has not been included in this overview. Politically and technically, Mexico is not part of Central America. However a box is offered with a general description of the policy and legal situation of ABS in Mexico.

- adopt measures to the maintain of natural habitats and their species;
- provide – individually or cooperatively with other states or international organizations – additional funds to support national and regional activities related to the conservation of biodiversity;
- promote and support scientific research in national universities and regional research centres;
- promote public awareness in each nation on the need to conserve, use and develop the biological riches of the region;
- facilitate the exchange of information among national institutions, Central American countries and international organizations;
- ensure that each state develops its national biodiversity strategies to create and manage the protected areas;
- create conditions to complement *in situ* conservation through *ex situ* conservation and facilitate the establishment of botanical gardens, germplasm banks and zoos to regulate and control collections; and
- promote and stimulate the development of new technologies to conserve and use biodiversity.

Most importantly, countries recognized that it is critical to create and strengthen national capacities and foster regional cooperation at the technical, scientific and cultural levels. This would facilitate use and conservation of biodiversity by local communities, and in turn implies revisiting regional integration policies and institutional structures.

In this context, access to and use of genetic resources in and from the region has become a key concern and policy issue for states. A common regional approach to ABS from the Convention for the Conservation of Biodiversity and the Protection of Wilderness Areas in Central America was considered. The main arguments for the need of a regional approach include:

- common biodiversity (and genetic resources) across most of the region;
- an ongoing general policy and legislative harmonization process;
- counterbalancing pressures from intellectual property rights (IPRs) policy and regulatory processes in the region;
- developing national biodiversity strategies and consolidating a network of National Biodiversity Commissions;
- advances in legislation on ABS in Costa Rica (Law No. 7788) and draft laws in Nicaragua;
- references in the Convention for the Conservation of Biodiversity and the Protection of Wilderness Areas in Central America, which clearly reflect a regional spirit to cooperate and harmonize ABS; and
- the potential of regional approaches to ABS, as highlighted by the CBD's Conference of the Parties.

This process started in 1997 with the meeting of an Open-ended Technical Working Group on Access to Genetic Resources in Central America. The conclusions of this meeting, formally supported by the CCAD, gave way to the draft Central American Agreement (Protocol) on Access to Genetic and Biochemical Resources and Related Traditional Knowledge (TK). It is important to note that early in the process due recognition was given to the differences between plant genetic resources for food and agriculture and all other forms of genetic resources (i.e. microbial, wild genetic resources) and the option of developing different rules for each.

This draft protocol, which establishes a minimum set of standards and rules that countries will have to implement according to their national legislation and specific needs, is based on the following key elements:

- Central American States are sovereign in their decisions regarding conservation and sustainable use of their resources (Preamble) and are entitled to determine ABS conditions (Article 5).
- Genetic and biochemical resources as well as the knowledge, innovations and practices related to them are of great relevance for the economic development of the states (Preamble).
- The protocol's objective is to regulate access to genetic and biochemical resources and knowledge, innovations and practices existing in any member state (Article 1).
- The protocol applies to all genetic and biochemical resources of which member states exercise property rights, whether in *in situ* or *ex situ* conditions (states may establish special rules for *ex situ* materials) as well as to related knowledge, innovations and practices of indigenous communities (Article 3).
- Human genetic resources, traditional exchange of resources (among communities) and uses other than as a source of genetic resources are excluded from the scope of the agreement (Article 4).
- States will determine – in accordance to their national legislation – the rights over biological and genetic resources (Article 6).
- States – through the National Competent Authority – will, when applicable, recognize and protect TK, innovations and practices of indigenous and local communities (Article 7).
- The protocol must be applied in accordance with international rules (CITES, phytosanitary measures and general trade rules) (Article 10).
- Each country – according to their national legislation – will determine a specific ABS procedure and authorization mechanism (Article 12).
- Elements of the procedure could include: an application; PIC; conditions for access; administrative fees; access restrictions; public participation; registers; information and recognition of other member states' interests; and use of MTAs and framework access agreements (Articles 13–25).
- The National Competent Authority will issue a Certificate of Origin, which determines and proves legal access to resources and knowledge (Article 21).
- The protocol establishes basic principles for the protection of TK: right to say “no” due to cultural, religious or spiritual considerations; PIC for use of knowledge; determination of any *sui generis* rights (Articles 28–35).
- A Central American Working Group on Access to Genetic and Biochemical Resources and Traditional Knowledge is created as an institutional structure to support implementation of the protocol (Article 39).

The protocol provisions should not constitute a barrier to trade and commerce. The political negotiation process for the adoption of the protocol had still to be initiated at the time of writing. It is, however, important to countries developing their ABS laws and regulations.

Box 1. Stages in the protocol access procedure

Each country will specify its access procedure, but the protocol proposes the following procedural elements:

- Access application (presented by a national or international, legal or natural person to the National Competent Authority) (Article 14).
- Contents of the application: identification of the applicant; detailed information on uses of genetic resources; information on potential dangers of access activities; purposes of access activities (including commercial activities); proposed mechanisms for benefit-sharing; national counterparts; geographical area where activities will be undertaken), potential uses of the resources; knowledge, innovations and practices of communities that may be related to the genetic resources); identification of the provider of the genetic resources; proposed monitoring mechanisms; and any other information that the authority may require (Article 15).
- Payment of fees (Article 18).
- Conditions of access (to be included in the access contract): limits to the quantity of samples that may be exported; conditions for participation of national researchers; technology transfer mechanisms; submission of information regarding resources and related knowledge; deposit of duplicates; communication of results of research and development activities; terms of transfer of materials to third parties; strengthening of institutional capacities; reports on commercial uses; and compromises to comply with environmental obligations. The conditions for access should constitute a fair and equitable sharing of benefits (Article 19).
- Elaboration of an access contract, a framework contract.
- Indigenous peoples' TK, innovations and practices, if used, will require the PIC of these communities.

A regional framework on industrial property

Patents, especially as applied to biotechnological inventions are very closely related to the issue of access to and use of genetic resources, and to the development and protection of research and development technologies. A draft Central American Patent Convention was prepared in the late 1990s, with the financial support of USAID.

This draft convention establishes a uniform industrial property regime for all countries in Central America. It will not replace existing national legislation on patents and industrial designs, but its provisions will supersede national laws if incompatibility arises (Article 137).

Patentability exclusions only include biological processes as they occur in nature and do not imply human intervention, except for microbiological processes (Article 4). Plants and animals (including varieties and races) are not expressly excluded from patentability, which leads some analysts to conclude that they may be patentable. Protection by patents of biological material will extend to any biologically derived material (which possesses the same characteristics) through multiplication or propagation obtained by the corresponding procedure (Article 41). When the patent covers a procedure to obtain a biological material with specific claimed characteristics, the protection will extend to the product obtained using the procedure (Article 40). In cases where the patent protects a specific gene sequence or biological material that contains this sequence, the protection will extend to all the products that contain the sequence or material and express the genetic information.

These draft provisions are a clear drive towards TRIPS to strengthen and extend considerably the scope of patent protection (as applied especially to biotechnological inventions). They will eventually have an effect on proprietary rights regarding the region's genetic resources and indigenous peoples' TK.

National experiences

Costa Rica

Legal status of genetic resources. According to Law 7788, Biodiversity Law (1998), genetic and biochemical resources are the property of the state. They are public property goods (not

in terms of IPR public domain), whether located on private or public lands and regardless of property regimes over biological entities that may contain them.

Law 7317, Law for the Conservation of Wildlife (1992), also determines that wild fauna are of public property and part of the national patrimony. Research and development in genetic resources, species, races, botanical varieties and wildlife, and all genetic transformation in species and plant varieties, is declared of public interest (Article 3). The production, management, extraction, commercialization, industrialization and use of genetic material of wild flora and fauna, their products and subproducts are of public interest and national patrimony (Article 4).

Law 7788 applies to “...elements of biodiversity which are under sovereignty of the State [...]. The Law will specifically regulate the use, management, related knowledge and the distribution of costs and benefits derived from exploitation of elements of biodiversity” (Article 3). Article 6 further specifies that “... biochemical and genetic properties of biodiversity elements are of public property. The state will authorize exploration, research, bioprospecting, use and exploitation of elements of biodiversity which are public property goods and the use of all biochemical and genetic resources, through access norms established in Chapter V ...”.

Every research and bioprospecting project in Costa Rica will require an access permit in accordance with Law 7788 rules and principles (Articles 62 and 69). Exceptions are provided in the case of access to human genetic resources, exchange of resources between indigenous and local communities (when these are non-profit exchanges) and public universities (which have a year to adopt institutional policies on non-profit ABS activities) (Article 4). In all other cases, natural and legal persons will be required to follow access rules under Law 7788. If research implies an inventory or a taxonomic activity, this type of activity will not fall under the scope of access regulations, but under Law 7317.

Until the enactment of Law 7788, in practice, access to genetic and biological materials was regulated by Law 7317 and its implementing regulation (Regulation 26435 – MINAE, 1997). Collecting licences issued by the Directorate of Wildlife of the National System of Conservation Areas (SINAC) for flora and fauna resources regulated access to Costa Rica biodiversity elements (including genetic resources). The licensing implied completing a form (with information regarding: researchers’ data, address, university or institutional affiliation, description of the project, area and location of project, duration, objectives, services required from the area and a declaration regarding non-commercial purpose of research), and a public consultation with local stakeholders in the area concerned. The process (from presentation of the application to approval) generally took about a month. Currently, a fee is charged for research activities (Decree 30343 – MINAE, 2002). SINAC will issue licences for commercial (commercial nurseries), scientific (teaching and taxonomy) and subsistence purposes (local communities).

It should be noted that, in 1998, the Ministry of the Environment and Energy initiated a Constitutional Action against Law 7788 (Constitutional Action No. 98-006524-007CO-M). Substantial provisions regarding access procedures have not been challenged, but the newly created institutional framework to govern access issues has. The powers of the National Commission for the Management of Biodiversity (CONAGEBIO) for the formulation and coordination of access policies have been challenged as unconstitutional, as has its powers to independently manage public funds. Resolution of this action is still pending and the implementation and operation of the new access procedure has been substantially delayed, even though the technical office responsible for approving access applications has been formally established.

Access to genetic resources under the Biodiversity Law and its regulation

The Biodiversity Law and, especially Executive Decree 31524 (15 December 2003) of MINAE, General Norms on Access to Biochemical and Genetic Resources of Biodiversity establish the detailed legal framework for access to genetic resources in Costa Rica.

The Executive Decree seeks to: regulate access to genetic and biochemical resources and related TK, innovations and practices; ensure benefits are shared with all sectors of society; protect *sui generis* community intellectual rights; facilitate access for research and development purposes; and promote transfer of technologies (Article 1).

Article 2 of the Decree further specifies Law 7788 and determines that ABS rules apply to genetic and biochemical resources as well as genetic elements, whether wild or domesticated, terrestrial, marine, in continental waters or in the air, in *ex situ* or *in situ* conditions, which are part of the national territory as defined in Article 6 of the Constitution, whether public or private property. The decree will also apply to TK, innovations and practices (to be regulated) and will ultimately ensure an equitable sharing of benefits derived from access to and use of these resources and knowledge.

Box 2. The National Institute for Biodiversity (INBio)

INBio is a civil society organization that contributes to the conservation of biodiversity by generating information about species, ecosystems and sustainable use of biodiversity. Its institutional mission is to 'promote further awareness about the value of biodiversity to support its conservation and enhance the quality of living of human beings'. INBio operates in six areas: inventory and monitoring; bioprospecting; bioinformatics; conservation; economic valuation; and 'bioalphabetism'.

Bioprospecting in protected areas is a key activity of INBio. It captures and generates bioinformation, systematizes it and transfers the results. INBio operates by assessing market demands, identifying key partners and establishing Collaboration Research Agreements. These agreements are negotiated on the basis of the following criteria: access to materials, compensation, technology transfer, training and non-destructive use of resources.

INBio's activities have been undertaken under the Law for the Conservation of Wildlife. Its activities have therefore been authorized by the Directorate of Wildlife as part of a Covenant with the Ministry of the Environment and Energy. This Covenant incorporates CBD and Law 7788 key principles and determines a framework Prior Informed Consent of the State (PIC). All Collaboration Research Agreements under the Covenant include a set of monetary benefits (all research budget is covered by the partner institution – almost always for commercial or industrial purposes, 10% of the budget is transferred directly to the MINAE for its use in protected areas, milestone payments, royalties (the percentage agreed with the partner is split equally between INBio and MINAE). Non-monetary benefits include technology transfer, training, infrastructure and equipment.

INBio's foreign partners include: Cornell University, National Cancer Institute, TEC, UMASS, EARTH, University of Strathclyde, National Institutes of Health, NASA and Florida Ice Farm. National partners include mostly companies such as Agrobiot S.A, Laboratorios Lisan S.A, La Gavilana, Industrias Caraito S.A Bouganvillea S.A, Follajes Ticos S.A.

Research in INBio is on secondary metabolites, enzymes, proteins, enzyme inhibitors, bionematocides and compounds for pharmaceutical, insecticide and cosmetics purposes. Validation of medicinal plants for gastrointestinal use is also part of its work.

As a result of its activities, which began in 1991, INBio has enabled the:

- generation of research budgets of US\$ 800 000 per year,
- transfer of economic resources to conservation areas (almost US\$ 600 000),
- generation of patents,
- transfer of research equipment valued at US\$ 2 000 000,
- *in situ* training of scientists,
- transfer of technologies, and
- generation of negotiation skills and expertise.

Genetic resources are defined as any material from living organisms that contains functional units of heredity and is under management of communities or research, or used through biotechnology of actual or potential value. Genetic elements are defined as all material from plants, animals, fungi or microorganisms that contain functional units of heredity. Finally, biochemical resources are defined as material derived from living materials that are used because of their actual or potential value, or certain characteristics, such as molecules or clues in their design.

In terms of exclusions (exceptions to the ABS regime), Article 3 establishes that biological resources (not utilized as a source of genetic or biochemical component, i.e. used for consumption purposes) will be regulated by specific laws and regulations (including fisheries, forestry, etc.). Traditional exchange among communities will also be excluded from the scope of ABS provisions.

CONAGEBIO is recognized as the National Competent Authority for all ABS purposes. It has ABS policy development and proposal faculties, and also will act (through a technical office) as the entity that will process, approve or reject and monitor access-related activities. It will also act as the National Focal Point on ABS under the CBD. CONAGEBIO may use external advisors (Article 5).

Access procedure

According to Article 7 of the Executive Decree, three types of permits may be granted for access purposes:

- basic research (which includes all activity implying “examination, classification or increasing knowledge over biological elements in general or their specific genetic or biochemical characteristics, without immediate interests in the commercialization of its results”);
- bioprospecting (which includes the “systematic search, classification and research for commercial purposes of new sources for chemical compounds, genes, proteins, microorganisms or other products with real or potential value which are found in biodiversity”); or
- commercial (which will enable the interested party to make use of genetic or biochemical resources (or genetic elements) with commercial purposes, without necessarily being an initial basic research phase as part of the application).

Each type of permit implies a different set of requirements. Article 7 also establishes that when basic research becomes bioprospecting and when bioprospecting turns into commercial use, applicants will need to modify their applications to the specific requirements of each type of permit. This raises a series of questions regarding when and how these different stages actually materialize.

All interested parties should present CONAGEBIO with an application that will include: name of applicants; type of permit(s) requested; identification card; legal powers; copy of receipts of payment of fees; and similar general information in order to clearly identify the party (Article 9.1). Following this basic application, a technical guide (in the form of an Affidavit) should also be presented. The guide should contain the names of researchers involved in the project, objectives of the project, geographical area where activities will take place, time, type of material which will be sought, scientific methods to be used, national counterpart, potential destination of resources, use of TK, previous studies on materials to be sought (if they exist), potential environmental impacts of activities, work plan and a copy of the project plan (9.2).

Important features of the access procedure are PIC and MAT. These should be reflected in a model contract (proposed by the technical office of CONAGEBIO) between the applicant and Regional Councils of Conservation Areas, an Indigenous Authority, a Local Authority or the owner of a land property or *ex situ* collection, or INCOPESCA, in the case of coastal

marine areas (Article 9.3). These contracts seek to safeguard the interests of legal and natural persons on whose lands or territories access activities may take place (providers).

These contracts may include (as a recommendation by CONAGEBIO): clauses regarding objectives of research, bioprospecting or commercialization, areas of research, number of researchers, type of materials to be used, methods, a price for samples collected, time, destination of materials, commitment by interested party to recognize the origin of materials in publications and research papers, conditions for use of TK and terms of a cultural impact study (where applicable), monetary benefits to be distributed and other terms which may be deemed necessary. In the case of research or bioprospecting, a fixed 10% will be part of the monetary benefits (resulting from the research budgets). PIC and MAT must be fully discussed with the providers of the materials.

In the case of basic research or bioprospecting, an applicant will additionally present CONAGEBIO with a commitment that if activities change in their nature, the applicant will comply with existing provisions to provide CONAGEBIO, the conservation area and provider with a copy of research results and deposit up to 10% of the research or bioprospecting budget (according to agreed terms). In the case of commercial use, there are three additional requirements: a description of the commercial use of the target genetic resources (or related TK), general information about the economic feasibility of the project, and a commitment to share up to 50% of the royalties in favour of the National System of Conservation Areas, communities, owners of the land or *ex situ* facilities, depending on where resources were effectively accessed. If the provider is the owner of the resource that contains the genetic or biochemical resources, they will pay up to 50% of royalties in favour of CONAGEBIO.

Article 11 of the Executive Decree establishes a special type of authorization. In the case where a commercial use becomes constant (i.e. an access permit is required covering the same resource at least six times in a period of five consecutive years), the applicant will need to apply for a concession. The technical office will submit the application to the ministry for its approval (or denial).

The technical office of CONAGEBIO evaluates the application (Article 13) and will use public interest and precaution as criteria for this evaluation (Article 14) and, eventually, the granting of the permit. An access permit does not exclude the party from complying with specific regulations regarding export of plants, seeds and microorganisms (Article 18).

The technical office of CONAGEBIO will also verify PIC and MAT terms (Article 12). If the application is approved, an "access passport" is issued that authorizes the interested party (the applicant) to enter the area where activities will take place (Article 13). This approval includes details of duration of the permit, the indication of the need to deposit up to 10% of the research budget and up to 50% of royalties, indication of the need for the applicant to present reports, and any restriction or condition the technical office may deem necessary. Applications and resolutions will be published on the CONAGEBIO Web page.

CONAGEBIO will authorize covenants and contracts signed between private parties (natural and legal persons), nationals or foreigners, that imply access to genetic and biochemical resources. These will need to adapt to specific provisions of Law 7788 and the Executive Decree. Permits may last for 3 years, with the possibility of extension. Public universities may elaborate framework covenants with the technical office of CONAGEBIO.

The technical office will issue a Certificate of Origin or Legal Provenance as a means to certify legality of access. The certificate will include: date of access, owner of resources, type of material obtained, quantity, and related TK. It will also indicate that the party has effectively complied with access legislation in Costa Rica (Article 19). This certificate may play a relevant role in mechanisms for defensive protection (i.e. patent applications).

Certain restrictions may apply to permits, concessions or covenants (Article 24). These are non-transferable. According to the precautionary principle as recognized in Law 7788, criteria for determining restrictions may include: endangered species, endemism, vulnerability or fragility of ecosystems, negative effects of activities on human health, ecosystems and communities, and geographical areas that might be considered as strategic. Access to genetic resources for military uses, terrorist use or as the basis for “terminator technologies” is strictly prohibited. Legislation for conservation areas also establishes specific situations where access to biological and genetic resources is prohibited.

CONAGEBIO will develop a specific regulation on access to genetic and biochemical resources deposited in *ex situ* facilities (Transitory Provision 1). No permits will be issued for access to materials deposited in such facilities until the regulation is in force.

Intellectual property and protection of traditional knowledge

Costa Rica’s Patent Law (Law 6867 of 1983 – revised in 2000 to comply with TRIPS’ standards) determines that biotechnological inventions may be patented. Plant varieties will be protected by a special law. Exclusions from patents include animals and plants and essential biological procedures to produce plants or animals.

Law 7788 has incorporated a set of provisions regarding intellectual property. Article 78 specifically determines that “intellectual property rights are protected through: patents, trade secrets, plant breeders’ rights, *sui generis* community intellectual rights, copyright and farmers’ rights”. It excludes from any form of protection: DNA sequences, plants and animals, microorganisms that are not genetically modified, essential biological procedures for the production of plants and animals, natural cycles or processes, inventions derived from related knowledge, traditional or cultural biological practices in the public domain, and inventions that if exported commercially as a monopoly might affect agricultural products or processes that are critical for the health and food of Costa Rican citizens.

In this context, Article 25 of the Executive Decree establishes that the technical office will oppose the register of patents, trade secrets, plant breeders’ rights, copyright, community *sui generis* intellectual rights, farmers’ rights or others, if the authorized institutions to provide with these types of protection do not comply with the requirements of Article 80 of Law 7788.

Law 7788 also establishes a set of principles relating to *sui generis* community intellectual rights, which seek to protect TK, innovations and practices. These rights exist *per se* and are legally recognized solely on the basis of the existence of a cultural practice or knowledge related to genetic or biochemical resources. These rights do not require a formal declaration, recognition or registration. Communities will determine the specific content of such rights. Transitory Disposition 2 of the Executive Decree establishes that no access permits will be granted when activities include the use of knowledge, innovations and practices of communities, until such time that a regime for the protection of communities rights is enacted.

El Salvador

El Salvador does not have specific legislation nor rules regarding access to genetic resources, though general legislation does address the issue. Intense activities have been undertaken with a view of developing laws and regulations on ABS, where the Ministry of the Environment and Natural Resources will have full competence and regulatory powers.

The National Biodiversity Strategy (2000) focuses on policy proposals regarding forests, natural protected areas, management of coastal marine areas, science and technology and environmental education (under the responsibility of the Ministry of Education). There are no references to ABS.

However, there is a recently concluded (2002) Strategy for the Strengthening of Capacities on Access to Genetic and Biochemical Resources of the Ministry of Environment and Natural Resources. The Strategy's mission is to strengthen the capacities of the ministry in the management and application of a legal framework on ABS. Its key strategic components are training, coordination, information management, and communication and awareness.

General legislation

Article 66 of Decree 233, the Environmental Law of March 1998, establishes that "access to, research, manipulation and utilization of biological diversity can only take place with a permit, licence or concession issued by the competent authority in the administration of the corresponding resources, to ensure protection and conservation under this law, special legislation and international conventions ratified by the country".

This law also defines genetic resources as any material of animal, plant or microbial origin that contains functional units of heredity with potential or real value (a similar approach to CBD).

The Law for the Conservation of Wildlife (1994, revised 2001) and the Forest Law (1995), determine that wildlife and forest resources, respectively, are part of the natural patrimony of the nation and the state is responsible for their management and protection. According to the Law for the Ordinance and Promotion of Fisheries and Aquaculture (2001), hydrobiological resources (marine and from continental waters) are also part of the nation's natural patrimony. Genetic resources from all sources would therefore be part of this patrimony and the state has rights over them, which it will exercise in regulating conditions and terms for accessing them. However, inasmuch as these resources may be on private lands or indigenous, they may be part of biological resources over which communities have specific rights. Any interested party will have to, at the very least, request these owners for permission for access to the genetic materials.

Decree 233 also makes specific references to issues related to genetic resources when it regulates Environmental Impact Assessment (EIA). All legal and natural persons will require to undertake an EIA when biotechnological projects or activities may be involved, or when these include genetic manipulation or the development of genetically modified organisms. An environmental permit is thus required in these cases, which will be issued by the Ministry of the Environmental and Natural Resources (Articles 21–22). Article 68 also determines that security measures will be applied by the ministry to ensure safe development of new plant varieties generated through biotechnology and to minimize potential impacts on native biodiversity.

Article 3 of Executive Decree 17 (2000), the implementing Regulation of the Environmental Law, recognizes the ministry as the National Competent Authority on all environment-related issues. The ministry is responsible for the granting of permits, licences and concessions for access to and use of natural resources (logically including genetic resources). It will also approve the environmental permit mentioned earlier. Article 93 of the regulation also calls for the ministry to protect the genetic patrimony of El Salvador by ensuring the protection of certain physical areas that may serve as a genetic reserve for the country.

There are no specific procedures for access to genetic resources, but the Law for the Conservation of Wildlife includes provisions on access to and use of biological resources. Article 8 establishes that "all utilization of wildlife, including hunting, reproduction, import, export, collection and possession for any purpose, will be regulated by corresponding regulations and will be administered by the Ministry [of the Environment] in coordination with organisms or institutions related to the matter".

The draft proposal on elements for a procedure on access to wildlife genetic and biochemical resources

This proposal seeks to regulate access to genetic and biochemical resources and TK (and benefit-sharing) with a view to ensuring participation in benefits, proposing a transparent framework for access, ensuring the conservation and sustainable use of biodiversity, maintaining the quality of life for citizens, ensuring creation and development of capacities, promoting technology transfer and strengthening the negotiating capacity of El Salvador. It reflects basic underlying principles: conserving the genetic patrimony of El Salvador, and ensuring the sovereignty, PIC, integrity of the cultural patrimony and participation of nationals in social and economic benefits.

The scope is “genetic and biochemical resources associated with wildlife and knowledge, innovations and practices under State sovereignty, whether in *in situ* or *ex situ* conditions”. Human genetic resources are excluded, as are traditional exchange (ancestral) among communities. Also excluded are genetic resources under the FAO International Treaty, biological materials that will not be used as a source of genetic and biochemical resources, and all activities related to taxonomy, inventory, monitoring and systematics. This relates to two types of access applications: one for academic research and a second for industrial use, with different conditions.

The General Directorate of Natural Patrimony of the Ministry of the Environment and Natural Resources is the National Competent Authority for access-related matters. The procedure is as follows: an application is submitted to the Directorate; information and access conditions are analyzed; preliminary approval made; an access contract must be negotiated between the applicant and the ministry (for MAT and PIC); contracts are registered with the Directorate and a permit is issued (and published in the official legal gazette).

Intellectual property laws

The Law for the Promotion and Protection of Intellectual Property (1993) is one of the few laws that does not expressly exclude from patentability plant varieties and essential biological processes for their generation. Thus, plant breeders are awarded patent protection, which is arguably stronger than plant breeders’ right but, at the same time, meeting patent requirements (novelty, inventiveness and industrial application) may be more complicated.

There are no exceptions in the law regarding inventions that make use of biological materials. Exceptions focus on use of inventions for pure research, education and private purposes, with extinction of rights once products have been commercialized for the first time. Patents are granted for 20 years.

Guatemala

General genetic resources policy framework

The National Strategy for the Conservation and Use of Biodiversity and Plan of Action (1999) is the main guiding policy instrument regarding biodiversity conservation and sustainable use in Guatemala. The Strategy process was coordinated by the National Coordinator for Biological Diversity (CONADIBIO) which, in turn, was formed by the National Commission for the Environment (CONAMA), the National Council for Protected Areas (CONAP), the Association of Natural Resources and Environment Organizations, San Carlos University of Guatemala, private universities and the Committee of Trade, Industry and Financial Associations. The process itself involved a wide range of stakeholders, including indigenous communities, NGOs and municipalities.

The Strategies focus on achieving *in situ* conservation; generating wealth and satisfying citizens’ needs (especially with regard to agricultural needs); recognizing biodiversity’s

cultural, ecological, economic and spiritual values; and ensuring that biodiversity is used equitably by Guatemalan citizens and for their benefit. The Strategy seeks to “orient, order and coordinate the actions of different actors related to the management of biodiversity in order to ensure its sustainable use and conservation”.

One of the key guiding principles of the strategy is to ensure an equitable sharing of the benefits derived from the use of biodiversity. In this regard, “the benefits derived from the use of all components of biodiversity – ecosystems, species, genes – must be equitably distributed among Guatemalan citizens in accordance with their relations and rights over the component used, as well as the knowledge applied in its utilization. Equitable benefit-sharing should consider gender, age, ethnicity, socio-economic level and place of origin”.

An Area of Strategic Action of the Strategy includes Use and Valuation of Genetic Resources (Section 5). Specific objectives are proposed for six programmatic areas, considered below.

Institutional development (programme area 5.1)

The main objective is to “develop institutional mechanisms to orient and coordinate actions for the conservation and sustainable use of genetic resources”. This will require the establishment of a National Programme for Genetic Resources (PRONAREGE) (5.1.1) which could be coordinated by the National Commission for Plant Genetic Resources (CONARFI, created in 1998). The programme will streamline governmental activities related to conservation, research, development, production and commercialization. One of the key functions of CONARFI will be to coordinate the implementation of the strategy and develop access to genetic resources policies and legislation. A second component of this programmatic area will be the creation and establishment of a Department of Wild Genetic Resources, under the management of CONAP.

Property rights and access to knowledge and genetic material (programme area 5.2)

This seeks to “recognize and regulate individual, peoples and the country’s rights over genetic resources and related knowledge”. This goal will include the creation and establishment of an ad hoc Temporary Commission on Property Over Genetic Resources (5.2.1). This multisectoral commission should develop a *sui generis* regime regarding property of genetic materials and related knowledge. A second action to be undertaken is the development of a legal regime for the recognition of property rights over genetic material and local knowledge (5.2.2). This will entail defining, limiting and recognizing property rights of the state, indigenous peoples and breeders over genetic material generated at any time in history. According to this action, this regime is critical for future regulation of access to genetic resources. Finally, a regime on access to genetic and biochemical resources needs to be designed and developed (5.2.3). This is due to constant demand for and extraction of genetic resources. The National Programme for Genetic Resources will carry out and coordinate this participatory process.

Bioprospecting and adding value to wild genetic resources (programme area 5.3)

This programme seeks to “create a system to identify, utilize and add value to genetic resources and their products”. An institutional model is to be created in order to regulate and promote bioprospecting (5.3.1). This institutional structure will also carry out bioprospecting activities. It needs to be based on agility in its operations, and consider the roles of CONAP (competent for granting access permits for wild resources) and the Ministry for Agriculture, Livestock and Feed (MAGA) (competent for granting access to agricultural resources, including livestock). An institutional network of universities, private enterprises, etc., for bioprospecting and adding value is also envisioned (5.3.2). Inventories of biodiversity in the wild are also envisioned as a means to support and complement

bioprospecting initiatives (5.3.3). Finally, specific exploration, collection and evaluation of species and varieties from the wild will be undertaken on the basis of agreements between the institution responsible for bioprospecting and interested parties (5.3.4).

Strategic conservation of genetic resources (programme area 5.4)

This programme's objective is to "conserve endangered domesticated genetic resources and their wild relatives [...]" and "... support food security of the population through the conservation and availability of genetic material". *Ex situ* conservation should complement *in situ* measures, and wild genetic resources conservation will be preferentially undertaken through the use of protected areas and areas of special interest for conservation purposes. A national agenda for the conservation of genetic resources will determine priorities and institutional arrangements for conservation of genetic resources (5.4.1). The National Programme for Genetic Resources will be responsible for identifying institutions and areas where national genetic resources are conserved, and *ex situ* sources where material may be available; compiling national inventories; defining conservation mechanisms; and identifying of germplasm banks in Guatemala, El Salvador and Costa Rica.

Long-term *ex situ* conservation through agreements and alliances is another means to achieve this goal. Agreements with CATIE (Costa Rica), CENTAG (El Salvador), CIP, CIAT and CIMMYT could pave the way to support *ex situ* conservation in the country (5.4.2). Institutional strengthening of existing *ex situ* conservation facilities in the medium and short terms will also support the achievement of this overall objective (5.4.3). A national programme for *in situ* conservation of agroecosystems and wild areas is seen as another potential conservation mechanism (5.4.4). Identifying certain geographical areas and resources found in traditional settings, registering these sites in the CONAP Register of Areas of Interest for Conservation, and the development of incentive mechanisms, could also serve towards conservation. CONAP, MAGA and the National Programme will be responsible for this activity. Conservation of genetic resources requires complete and detailed inventories of useful domesticated species and their wild relatives (5.4.5), for which CONAP, MAGA and universities will be responsible. Criteria for selection will include actual use and utility, endemism and specific threats.

Characterization, assessment and enhancement of genetic resources (programme area 5.5)

This programme seeks to "... identify and develop the potential of genetic resources for the country" in order to conserve genetic resources and make them available for human use. Identification and evaluation of prioritized genetic resources – based on material held in germplasm banks – facilitates breeding programmes. These activities will be responsibility of universities, National Forest Institute (INAB), Institute of Science and Agriculture Technology (ICTA) and PRONAREGE (5.5.1). Databases incorporating the characteristics of genetic material need to be available for farmers and breeders. They should be integrated into a network under the responsibility of the PRONAREGE (5.5.2). Improvement in and breeding of underutilized native species and varieties to promote their incorporation into local and international markets is another key action that needs to be undertaken. Farmers should be involved in these processes, which will be under the auspices of PRONAREGE, universities, INAB and ICTA (5.5.3).

Diversification of markets based on underutilized species and varieties (programme area 5.6)

Generating socio-economic benefits, increasing and diversifying production and consumption are fundamental to ensuring food security and reducing production risks. To achieve this, it is important to identify and prioritize opportunities regarding markets and potential materials (species and varieties). This implies a market analysis and an assessment

of the existing potential of these species, which NGOs, companies and MAGA should undertake (5.6.1). Diversifying production of native species and varieties requires state support (credit, technologies, access to evaluated and improved materials, organization and planning) (5.6.2). Enhancing traditional commercialization systems enables the production system to adapt itself to offer capacity. Strengthening these systems can ensure that diversity remains a key factor in production of traditional crops and varieties (5.6.3). Finally, social marketing of native crops and varieties among the wider society could have an impact on consumer patterns. This could be achieved through agrobiodiversity fairs, education in the media, and formal education (5.6.4).

Documentation and rescue of practices and ethnobotanical knowledge (programme area 5.7)

This seeks to “document, rescue and revalue TK and practices regarding production, commercialization and use of wild and cultivated native species and varieties”. TK is poorly documented. Hence the need to investigate and compile existing materials, promote collaborative research on these species and provide communities with the information generated (5.7.1). TK should be valued and recognized. This implies enhancing TK and practices, and improving the capacity to adapt and respond to present needs by involving and effectively engaging communities (5.7.2).

Access to genetic resources rules and practices

Guatemala lacks a specific ABS regime. However, there is evidence that institutions in Guatemala either obtain material *in situ* or transfer them. ICTA conserves pylons of medicinal plants and seeds, which are offered to the public (generally for immediate consumption or cultivation). Materials from the seed bank are also provided subject to the presentation of a letter of request (indicating amount of seed, purpose of the purchase, identification of the responsible person and requesting institution) and issuance of an authorization. Most requests are made by researchers and other seed banks. ICTA and other national institutions must comply with Ministerial Agreement 177/95, which establishes minimum standards for the management of and access to plant genetic resources.

The Law on Protected Areas determines that CONAP should any research activities on wild biological materials (Article 35). CONAP authorizes research in protected areas (Article 47) and issues permits for collection, capture, transport, research or commercialization of biological resources from *in situ* sources (Article 52). The Regulation implementing the law includes provisions for sharing of scientific research publications and a percentage of benefits derived from materials commercialized or patented (Article 26).

MAGA (through its Unit of Norms and Regulations) is the Competent Authority responsible for authorizing access to cultivated genetic resources in Guatemala. ICTA carries out the technical monitoring and follow up of field activities. CONARFI was established in 1998 as an intersectoral mechanism to coordinate activities related to genetic resources. However, it has not yet become institutionalized.

A formal assessment of the implementation of CBD in Guatemala – and of Article 15 in particular – in October 2001 reached the following conclusions (summarized) with regards to the ABS regime:

- Genetic materials and resources are being used in many forms.
- Formats are used by certain institutions to facilitate access; the information provided is limited to the names of applicants and resources sought.
- ICTA undertakes evaluations of imported materials, but activities by the private sector are mostly uncontrolled.

- Small farming communities have not benefited equitably from access to and use of their materials.
- No sanctions are enforced for unlawful use of and access to genetic resources.
- Workshops, seminars and meetings are needed as a means of raising awareness regarding policy and legal aspects of genetic resources.
- The National Biodiversity Strategy includes general guidance for the enhancement of *ex situ* conservation and cooperation with regional organizations.
- CONAP and MAGA have not fully fulfilled their obligation of providing the CBD Secretariat with information regarding ABS issues in Guatemala.
- CONARFI should undertake overall administrative activities in regards to ABS.
- The current legal framework does not provide for specific benefit-sharing measures regarding plant genetic resources for food and agriculture.

Law on Protected Areas

Article 1 establishes that wildlife is an integral part of the natural patrimony and that its restoration, protection and conservation, and the management of special designated areas, is of national interest. The use of flora and fauna includes search, collection, extraction and capture of specimens. All uses – though not specifically related to genetic resources – require an authorization issued by the National Council for Protected Areas. The regulation of the law does not refer specifically to benefit-sharing, though Article 26 establishes the obligation to share with the national authority any publication resulting from research.

Collection of germplasm for agricultural purposes was prohibited by Ministerial Accord 276/89 (1989). However, in the absence of specific regulations, in practice this prohibition has no effect.

Intellectual property

Article 1, Law 153-85, the Patent Law of 1985, excludes from patentability plant varieties and animal races, as well as essential biological processes for their generation (except if they are microbiological processes and their products).

Nicaragua

Nicaragua has no specific ABS laws and regulation, although there are numerous specific references to genetic resources in various national laws, drafts and policy instruments.

Legal status of genetic resources and the constitutional framework

The Constitution of Nicaragua (Articles 60 and 102) determines that natural resources are national patrimony. The concept of national patrimony, though not specifically state property *per se*, implies that all natural resources pertain to the nation and state. In representing the nation, it exercises domain (property) rights for the benefit of Nicaraguan citizens as a whole.

The National Environmental Policy and Action Plan

A process was initiated in 2000 to update and redefine the national environmental policy, some elements of which are applicable and relevant in the context of ABS policy. The National Environmental Policy and Action Plan was enacted through Executive Decree 25 (2001). Its guiding principles are as follows:

- Natural resources and biodiversity are the common patrimony of society and thus the state and all citizens have the right to and obligation to ensure their sustainable use, accessibility and quality.

- Use of natural resources and the environment enhances the quality of life and reduces poverty and environmental vulnerability.
- Environmental management is understood within the context of social equity and gender respect, and is founded on prevention.
- Citizen participation is essential in environmental management.

The Policy and Action Plan establishes that the state will:

- together with society, promote a development model based on a balance between economic growth and protection of biodiversity, which gradually reduces poverty and elevates quality of life for all, especially the most vulnerable sector of society;
- formulate, modernize and harmonize laws, decrees and regulations that facilitate decentralized, participatory and efficient environmental management;
- prioritize the prevention and the precautionary principles within the EIA process;
- protect, develop, manage and conserve Natural Protected Areas; and
- guarantee compliance with national and international obligations and ensure activities within its territory do not affect neighbouring countries.

An Annex to the Policy and Action Plan defines more specific actions with regard to biodiversity, including enacting a national law on biodiversity and the promotion of technology and biotechnology, and reviewing all existing biodiversity policies and legislation, especially with regard to Law 217 (discussed later).

General Law of the Environment

Article 54 of Law 217, General Law of the Environment of 1996, provides that natural resources are national patrimony and their use and exploitation are subject to its provisions, specific laws and regulations. Specific laws will govern access to and use and exploitation of different types of resources, including genetic resources. The state will have the discretionary power to grant exploitation rights over these resources through concessions, permits, licences and quotas.

It also establishes that it is an obligation of the state and all citizens to ensure the conservation and sustainable use of biological diversity and the national genetic patrimony in accordance with norms and principles enshrined in national law and international treaties and conventions signed and ratified by Nicaragua (Articles 62 and 63). Furthermore, it also recognizes that, in the case of indigenous and ethnic communities that provide genetic resources, the state will ensure that access to and use of these resources is in accordance with terms previously consulted and agreed upon with these communities. This follows Strategic Line 5 of the Plan of Action of the National Biodiversity Strategy (2001), which promotes the recognition of property rights of indigenous and local communities over their genetic resources.

Article 63 determines that biotechnology activities will require an authorization of the National Competent Authority (in accordance to a regulation still pending development and approval). These activities should ensure the effective participation of citizens, especially of those groups that provide genetic resources. It should also ensure sufficient information regarding applications, security measures and negative effects of potential manipulation of resulting organisms.

These general rules clearly determine state sovereign powers to regulate access, although the legal status of genetic resources is not expressly defined. The Constitution of 1987 determines that natural resources are national patrimony and Article 64 of Law 217 establishes that germplasm and native species (especially endemic species) are registered and patented in favour of the state and the peoples of Nicaragua. PIC is required for

communities on whose lands activities might take place, reflecting a general principle in the draft Biodiversity Law (prepared in 1996), which determines that indigenous communities have rights over their resources. There is a specific focus on biotechnological activities and how these make use of genetic resources.

The Supreme Court of Justice of Nicaragua has issued specific resolutions regarding the issue of domain and property over natural resources. It clearly specifies that the state has regulating powers over all natural resources and determines specific conditions for access to and use of these resources. A Supreme Court Resolution in 1989 clarified that the “national patrimony” is all goods and assets pertaining to the state (i.e. natural resources) and which the state destines for the social and economic benefit of citizens. Under the domain of the state are all those goods under public law rule and over which the state effectively exercises property rights, though in the context of the public and social good. The state may grant rights to private persons for their use and exploitation within the framework of specific rules and public law principles. It has the obligation and responsibility to ensure the preservation and conservation of natural resources.

National Environmental Policy and ABS

Executive Decree 25 – 2001 (March 2001) established a National Environmental Policy for Nicaragua. Specific biodiversity-related mandates are contained therein. These include enactment of the National Biodiversity Law and a Law on Science, Technology and Biotechnology, and the follow up and assessment of international conventions to further develop and regulate biodiversity-related aspects of Law 217. It addresses management and use at the ecosystem, species and gene levels.

National Biodiversity Strategy and Action Plan (NBSAP)

The NBSAP, adopted in 1996, establishes a series of strategic policy objectives aimed at the implementation of CBD. Prior to its formulation, a survey was made of genetic resources in Nicaragua. This served as the basis for the definition of coherent policies and strategic goals.

These goals include:

- adopting of a law on biodiversity, use and benefit-sharing as the foundation for a regulation on ABS (including the protection of TK), and a biosafety law (also in accordance with Law 217);
- ratifying the Biosafety or Cartagena Protocol;
- developing and enacting criminal environmental sanctions related to biodiversity, including sanctions against biopiracy and illegal trade in components of biodiversity; and
- developing policies aimed at conserving and using biodiversity, and the fair and equitable sharing of benefits derived from its use.

Institutional framework

The General Directorate of Biodiversity and Sustainable Use of Natural Resources of the Ministry of the Environment and Natural Resources issues authorizations and permits for bioprospecting activities in Nicaragua for wild biodiversity. Regional and local governments are also entitled to submit legal opinions and positions regarding the viability of projects that imply accessing and using biodiversity components, including genetic resources.

However, jurisdiction and competences concerning genetic resources is widely dispersed and conflicts occur. The following is a summary of the institutional structure that directly or indirectly relates to genetic resources:

- Nicaragua Institute for Agriculture Technology, responsible for research and technology transfer.

- Ministry of Agriculture and Forests, responsible for animal and phytosanitary measures; trade and distribution in seed; and technical assessment of new plant varieties.
- Centre for Seed Genetic Improvement, responsible for genetic improvement and seed production (especially forest resources).
- Minister of Promotion, Industry and Trade, deals with the IPR system (through the Register of Intellectual Property).
- Ministry of the Environment and Natural Resources (MARENA) administers biodiversity; provides technical opinions as part of the Qualifying Committee for the Protection of New Plant Varieties; elaborates technical regulations on biodiversity exploitation; registers innovations on biodiversity and centres undertaking genetic manipulation of biodiversity components; develops mechanisms for conservation, access to genetic resources, bioprospecting and scientific research; coordinates the formulation and implementation of the biodiversity policy; and participates in planning of seed trade and production, and in the planning of animal health and phytosanitary measures.
- Autonomous Regional Governments: participate in policy formulation with MARENA for regional planning of natural resources and the use and exploitation of resources within their jurisdiction; and approve contracts for use of biodiversity.
- Municipal Governments enact Municipal Ordinances on environmental matters under their competence; and give opinions in the process of contracting for the use of and access to biodiversity.

Intellectual property

Through Law 217 (discussed earlier), germplasm and each and all species (especially endemic species) in Nicaragua, are registered and patented in favour of the state and the people of Nicaragua for their exclusive and preferential use. The exact meaning and implication of this provision is unclear; it seems to reflect the concern of the state to ensure that its genetic resources are protected from third-party use and that through the use of a register and a form of patent, this might be achieved. Clearly, the patent system traditionally operates quite differently and on a case-by-case basis, where an invention (not a mere discovery) will be evaluated to verify that it complies with novelty, inventiveness and industrial application. Thus, the fact that species are patented in favour of the state should not be interpreted in terms of formal, traditional patents governed by IPR rules. This is a different right, which gives the state (and the Nicaraguan people), a type of exclusive right and domain power over their species.

Indeed, Article 8 of Law 354, Patent, Industrial Designs and Utility Models Law of 2000, determines that matter which is in nature (in a natural state) does not constitute an invention. Species would be excluded from patenting under classical IPR law.

This law also excludes from patenting essential biological processes for the production of plants and animals, except for microbiological procedures. When an invention refers to a product or procedure related to biological material (all biotechnological inventions), a deposit – in the country or abroad – of the material is required (in order to satisfy the disclosure requirement) (Article 22). Patents are granted for 20 years and yearly fees are required to maintain in force the patent right. Patents over biotechnological procedures extend to the resulting product (Article 45).

The scope of the patent is determined by the claims. The patent gives the holder the right to impede third parties from exploiting the invention without the authorization of the holder. The holder may act against any person who without their consent produces or fabricates the patented product, offers for sale or sells the product, imports the product, or uses a patented process or a product directly derived from that process. Research exemptions are in place for all types of inventions. There is also a “farmer’s exemption” in

the case when farmers need to use multiplication materials for further cultivation or direct consumption purposes. The Patent Law also applies to seeds and breeding materials.

It is generally accepted that biotechnological inventions are patented in Nicaragua. However, there are conflicting interpretations of the relationship between Law 354 (the Patent Law) and Law 271, which registers and patents in favour of the state and peoples of Nicaragua (in the case of biological materials).

Law 318, Law for New Plant Varieties of 1999, establishes the legal regime for the protection of plant breeders and new plant varieties. In 2001, possibly in order to comply with its international obligations under the TRIPS Agreement (and the Bilateral US-Nicaragua Agreement of 1999), Nicaragua adhered to the UPOV Act of 1978.

The breeders' right allows the holder to prevent the use, production, export, import, multiplication or donation of the reproduction and multiplication material of the protected variety. Authorization is also required in the case of ornamental varieties (or parts thereof) when used for purposes other than multiplication. A research exemption applies when the protected variety is a source of material for further genetic development, where farmers use the variety for reproduction or multiplication within their own field, and where a variety or its product is sold for human or animal consumption.

Initially, Plant Breeders' Certificates for new rice and tobacco varieties have been granted by the Register of Intellectual Property of the Ministry of Promotion, Industry and Trade (MIFIC). A Qualifying Committee for the Protection of Plant Varieties (created by Law 318) provides MIFIC with technical assistance in the evaluation of protection requirements (novelty, stability, distinctiveness, homogeneity).

The technical, formal and substantial review of a Plant Breeders' Rights (PBR) application involves MIFIC, the Ministry of Agriculture and Forestry (MAGFOR) (through the National Seed Directorate), the Ministry of Promotion, Industry and Trade (through the National IPR Register), Ministry of the Environment and Natural Resources (through the General Biodiversity Directorate), Nicaragua Institute for Agriculture Technology, and specialists of the National Agriculture University and the National Autonomous University (representing civil society interests).

Law 318 has been the subject of two constitutional challenges for two reasons: that it violates the Constitution in that it promotes privatization of the national patrimony, and that genetic erosion is a danger that needs to be prevented (under the Principles of Prevention, Precaution and Sustainability recognized in national legislation and international agreements). It is expected that these actions will not proceed, though the Supreme Court has not handed down a verdict in these cases. Law 318 does not seek to privatize native species nor the national patrimony, but to facilitate and promote research and genetic improvement.

A bilateral trade agreement between USA and Nicaragua (1999), following TRIPS' mandates, establishes that each contracting party will provide patents for any invention, products or processes, in all ambits of technology, when these are new, result from an inventive activity and have industrial application. Parties may exclude inventions from patenting if it is necessary to impede in their territories the commercial exploitation of inventions to protect the public order or morality (including human life and animal and plant health), or to prevent grave damages to nature or the environment.

Seed Law and its regulation

Law 280, Law for the Production and Trade of Seed, and its implementing Regulation, were enacted in 1998. Agriculture is the most important economic activity in Nicaragua and seed is therefore a strategic resource, critical for the nation's food security, and hence high quality seeds and plants are very important.

Law 280 seeks to “promote, norm, regulate and supervise activities related to research, trade and production of seeds and plants from nurseries ...”. The Ministry of Agriculture and Forests, through its General Directorate of Seeds, is the competent authority. The law applies to research, production, importation, exportation, distribution, trade, cultivation and transport of seeds and plants from nurseries.

The Law creates a National Seed System, which is administered by the General Directorate of Seeds. The system comprises the different components forming the different phases of the process of production and commercialization of seeds and nursery plants. This includes the initial phase of plant breeding and the production of new varieties, including the generation of new plant varieties, initial multiplication of these, and seed production, certification and training.

In relation to the system, MAGFOR has the following general functions to:

- design, formulate and develop seed production and commercialization policies;
- determine and supervise technical norms for the production of seeds and plants from nurseries;
- certify and regulate seed production;
- verify and certify the quality of seeds and plants from nurseries;
- develop and promote activities to stimulate seed and plant production; and
- promote training of seed producers and people involved in commercialization of seeds and plants from nurseries.

More specifically, the General Directorate of Seeds has the responsibility to:

- establish specific technical norms for seed certification and plants from nurseries (of different species);
- organize, structure, revise and actualize – with other national and international organizations – certification of seeds and plants from nurseries;
- participate in the National Seed Council (CONASEM);
- establish the register of plant varieties, producers, importers, exporters and distributors of seeds and plants from nurseries;
- coordinate and collaborate in the planning of national seed and seedling production;
- certify seeds and plants from nurseries for cultivation based on established certification rules;
- inspect the production and quality of basic seed and plants for nurseries;
- regulate and control trade in seeds and plants from nurseries;
- authorize the import of seeds at the experimental and commercial levels;
- publish annually the list of registered seeds authorized for production (whether national or imported);
- authorize the export of certified seeds;
- determine fees for different services related to seed production and registration; and
- apply penalties.

The National Seed Council is a support and consultation body for research, analysis and development of national policies in regard to production, research and trade in seed. It also participates in the evaluation of new cultivars created through research or introduced for commercial purposes.

The council comprises two representatives each from the Ministry of Agriculture, General Directorate of Seeds, and the private agricultural sector, and one representative each from the Ministry of the Environment, the Institute of Nicaragua for Agriculture Technology, the

National University for Agriculture, seed producers and the Committee for Integrated Pest Management.

To undertake genetic improvement of seeds or nursery plants certain requirements need to be met. The legal or natural persons should register with the General Directorate of Seeds and accept its monitoring and control activities. These persons or institutions must also:

- provide all information related to experimental work on genetic materials, validation of materials or production of certified or basic seed;
- register varieties and hybrids obtained through genetic improvement and validation;
- register the areas where multiplication of seeds or plants from nurseries takes place; and
- comply with the guidelines and recommendations of the relevant national authorities.

The draft Law on Biological Diversity

The Ministry of the Environment and Natural Resources (MARENA), with the support of IUCN, the Finland-Nicaragua Environmental Programme, UNDP and the Mesoamerican Biological Corridor, has formally presented the Executive Branch of Government with a draft proposal for a Law on Biological Diversity. The process for the development of the draft was initiated in 1996. In 2000, the General Directorate of Biodiversity of MARENA formed an interdisciplinary international working group to assess previous drafts and prepare a final version of the draft law. A further consultation among civil society in Nicaragua was undertaken in mid-2000 and new issues on biosafety, wildlife and environmental services were incorporated. The final draft, submitted by the Executive to the Legislative Branch was, at the time of writing, awaiting approval by Congress.

This draft law establishes specific ABS procedures and rules. ABS access contracts between an applicant and the INABIO, which will include conditions such as level of royalty payments, express PIC, transfer of materials to third parties and IPR restrictions. In the Atlantic Coast Autonomous Regions, their regional councils approve the contract, and in the municipal entities their views need to be taken into consideration. An accessory contract will govern the relationships between the applicant and indigenous groups or private bodies. These contracts will also incorporate conditions regarding the use of the intangible component (TK), where applicable. Persons seeking to undertake research or transfer materials for scientific or commercial purposes, sign Framework Agreements with INABIO.

Farmers' Rights are also recognized in the draft. Knowledge, innovations and practices of indigenous, local and ethnic communities are "cultural patrimony" and subject to PIC by these groups (realized in a non-exclusive accessory contract). The intangible component is defined as *Sui Generis* Community Intellectual Rights. No declaration nor registration is required for the recognition of these rights. This component is legally protected as a trade secret. A regulation will specify the contents and scope of these general provisions.

The final authorization (of the contracts) will be non-transferable and non-negotiable. All authorizations should be registered in INABIO. Biopiracy (and actions affecting Traditional Knowledge (TK) are sanctioned as a crime (with a penalty of prison and fines).

Panama

Biodiversity and genetic resources are key components of a series of recent legislative developments in Panama, following ratification of the CBD.

Property and domain over biodiversity and its components

The Political Constitution (1972) and the General Wildlife Law (1995, see analysis below) determine that natural resources (in general) are considered as part of the public domain. It

is not the IPR-related public domain but, rather, rights vested in the state as the representative and embodiment of the nation and its people.

General Environmental Law

Law 41, General Environmental Law of July 1998, establishes as a general principle that natural resources are of the public domain and social interest without prejudice of legitimate right acquired by private persons (Article 62). This basically means that the state has a right to regulate natural resources and take into account other rights that might be related to these resources (i.e. property and land rights).

The Law defines genetic resources as “a set of hereditary molecules whose function is generational transfer of information regarding natural heredity in living organisms. Their expression gives way to a set of cells and tissue which form the living being” (Article 2).

Institutional competences regarding access to and use of genetic resources are assigned to the National Environmental Authority. Article 71 of the Law determines that the National Environmental Authority “... will be the competent entity, based on the law and regulations, to norm, regulate and control access to biogenetic resources in general, with the exception of human species, respecting IPRs. To undertake this task it will develop and incorporate legal instruments and economic mechanisms. The right to use natural resources does not entitle the holder of the right to exploit genetic resources contained therein”.

A distinction is made between the natural resource (i.e. biological resources), over which a permit or authorization or concession may be granted, and the genetic resources, which may form part of the resource. The granted right will not imply rights over the genetic resources (this would imply a special regulatory regime for genetic resources). This distinction seems clear in the case of wild biological resources (because effectively, the state, in representation of the nation, exercises rights over these resources). However, this is not as clear in the case of cultivated resources. Traditionally it has been the Ministry for Agricultural Development that has had jurisdiction to regulate cultivated biodiversity or agrobiodiversity.

The Law defines “prospecting” (or biological exploration) as “exploration in natural wilderness areas in search of species, genes or chemical substances derived from biological resources to obtain medicinal, biotechnological or other products”. It does not specify explicit provisions to govern access to and use of species, genes and chemicals derived from biodiversity. These will probably be regulated as part of a specific law or regulation.

Access to and use of natural resources on indigenous peoples’ lands or territories (*comarcas*) must be coordinated between the National Environmental Authorities and traditional authorities of indigenous and local communities (Article 96). The state will respect, maintain and preserve knowledge, innovations and practices of communities as they relate to biodiversity, and promote their wider use with their participation by ensuring the equitable sharing of benefits from their use (Article 97). The *comarcas* and indigenous peoples have a right of use, management and traditional exploitation of renewable natural resources located on their lands and indigenous reserves created by law (Article 98). Their social, cultural and political integrity and spiritual values must not be affected by activities for exploration and exploitation of natural resources undertaken on their lands (Article 99).

The need to obtain an express authorization from the National Environmental Authority in the case of exploitation of natural resources – including genetic resources – in indigenous lands is complemented by the obligation to undertake consultation processes with communities and their representatives for the use of their resources and related knowledge. Benefit-sharing arrangements will also be decided and agreed upon as part of these participatory processes (Articles 101–103). Exploitation of natural resource projects (on indigenous lands) undertaken by community members will have preference over those presented by third parties (Article 104).

Marine coastal resources – including marine genetic resources – are national patrimony and their use, management and conservation are under the competence of the Panama Maritime Authority.

General Wildlife Law

Law 24, General Wildlife Law of June 1995, specifically declares that wildlife is part of the natural patrimony of Panama and that the protection, conservation, research, management and development of genetic resources are part of the public domain (Article 1). This does not mean “public domain” as in IPR law, but the right of the state over these resources and the faculty to grant a right of use over them. This law generally addresses the issue of species conservation and use. In this regard, as biological entities, specimens collected for taxonomic or even commercial purposes will require an authorization by the National Environmental Authority (through the Directorate of Protected Areas and Wildlife). This authority will also issue fishing, hunting and collecting permits. Non-compliance (i.e. collecting without permits or causing damage to specimens) may lead to criminal actions, which include sanctions of up to 6 months imprisonment and payment of heavy fines.

Any activity within indigenous community lands (comarcas) will require an express authorization by indigenous authorities.

National Environmental Strategy

The National Environmental Strategy was approved by Cabinet Resolution No. 36 of May 1999. The National Biodiversity Strategy (NBS) vision states that Panama “... possesses an adequate knowledge about biodiversity, which is used to support its conservation and valuation, at the same time it obtains benefits from its sustainable use and shares them equitably, respecting intellectual property”. This same vision was incorporated into the Plan of Action of the NBS of 2000. In this regard “... the benefits derived from the sustainable use of biodiversity should be equitably shared among all sectors of civil society, preferentially with local, indigenous and peasant communities [...]”.

Biotechnology

There is no specific legislation to regulate (promote, control, monitor) biotechnological development and activities in Panama, although there are institutions applying biotechnological methods in research, development and production activities. Biosafety is mostly concerned with the introduction of exotic invasive species, and the General Wildlife Law establishes certain requirements for the importation of exotic species and their introduction into the environment (Article 37).

The Institute for Agriculture Research carries out crop improvement in its field facilities in the Herrera Province. There is also evidence that private companies are exploring tissue culture techniques for mass production of varieties with high commercial value, including orchids, exotic flowers and other ornamental species. Industrial application of biotechnology is also an incipient activity.

Intellectual property

Law 35 on Industrial Property, 1996, establishes the patent regime for Panama. Article 15 excludes from patenting:

- essential biological processes for obtaining and reproducing plants, animals or varieties, where the National Direction of Intellectual Property (DIGERPI) of the Ministry of Commerce considers they affect morality, integrity or dignity of humans;
- plant species and varieties, and animal races and species;
- biological material as it exists in nature; and

- inventions related to live materials that are part of the human body.

Law 23 on the Protection of New Plant Varieties of 1997 established a legal regime for the protection of plant varieties, based on the UPOV Act of 1978 (which requires novelty, stability, distinctiveness and homogeneity). No recognition is given to essentially derived varieties. Farmers can re-use the breeding material in their own field (Farmers' Right) and researchers can use materials for further breeding purposes (Breeders' Exemption).

The Plant Breeders' Certificate is issued by DIGERPI and the Institute for Agriculture Research undertakes formal and mandatory examination of varieties and maintains the living sample. Once the period of protection ends (20 years for plants and 25 years for trees), the variety will pass into the public domain.

Protection of traditional knowledge

Article 77 of the Constitution recognizes that "national culture is represented by artistic, philosophical and scientific expressions produced by the Panamanian man over time. The state will promote, develop and protect this cultural patrimony". Article 77 and the CBD process (especially the review of article 8(j)) and the overall TRIPS review process can be identified as the foundation for progress made in Panama regarding the protection of TK.

Law No. 20 of 26 June 2000 of Panama creates the Special Regime for Intellectual Property over Collective Knowledge of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge, for which Executive Decree No. 12 of 20 March 2001 establishes the implementing regulation.

Scope

This legal regime seeks to protect collective IPR and TK of indigenous peoples over their creations, such as inventions, models, drawings and designs, and innovations contained in images, symbols and graphics, together with cultural elements of their history, music, art and traditional artistic expressions, all of which might be susceptible of commercial use. This is accomplished through a special system of registers and promotion and commercialization of their rights.

The regime also identifies elements of the Indigenous Cultural Patrimony, such as customs, traditions, beliefs, cosmovision, religion, folklore expressions, artistic manifestations, TK and any other traditional expression of indigenous peoples. These cannot be subject to exclusive rights of non-authorized third parties (through copyright, trademark, industrial models or other instruments); these instruments can be used by indigenous peoples.

"Indigenous Collective Rights" are defined as intellectual and cultural rights of indigenous peoples, referring to art; music; literature; biological, ecological and medical knowledge; and other aspects and expressions. They have no known author, owner nor date of creation, and are part of the patrimony of an indigenous group (*pueblo indígena*). Law No. 20 recognizes these rights over traditional dress and garments, musical instruments, music, dance, written or oral expressions, techniques for their creation and, in general, any and all manifestation of a traditional nature. These can be registered in order to preserve their originality and authenticity. To be protected, the objects need to comply with "cultural identification" (an intrinsic bond between the community and tradition) and susceptibility to commercial use (this potential condition is critical for the protection of the collective right).

Rights and administration

The Collective Register for Intellectual Property is a constitutive register by which the state confers an exclusive right to exclude third parties from the exploitation of the collective right resulting from TK or expression of folklore. The application can be presented to the

Dirección Nacional de Derechos de Autor del Ministerio de Educación (the copyright office), or to the newly created Departamento de Derechos Colectivos y Expresiones Folclóricas de la Dirección General del Registro de la Propiedad Industrial del Ministerio de Comercio e Industrias (Department of Collective Rights and Expressions of Folklore of the Industrial Property Office). The register application will be presented by the general national congresses or indigenous peoples' traditional authorities in order to protect their dress, art, music or any other traditional right susceptible of protection. The congress or authorities will also designate a formal representative.

In terms of content, the application for protection (which takes a standardized form) must include an indication that it refers to a collective right and pertains to national indigenous people, the technique used (if it refers to an object), a brief description of the tradition involved, an official act formalizing the request for an application, and a use regulation for the collective right, which includes: the indigenous people group(s) requesting the registration of the TK or object; authorization by the general congress or indigenous people's authority; the indigenous collective right sought (using the indigenous or official language); use(s) of the indigenous TK or object; history of the collective right; dependent communities or beneficiaries; and a sample of the object to be registered.

Procedures

An application is presented to the national authority and verified within 30 days. If information is missing, it will be requested (and must be provided within a maximum of 6 months). A new procedure must be initiated if this is not satisfied. When the application is complete and all conditions are met, the Collective Right is registered; the indigenous group or community who created and possesses the TK or folklore expression is recognized as the owner. The register will be in favour of the registering indigenous congress or authority, even if the objects to be protected could derive from various communities. In the case of knowledge, this could be common to various communities; hence, the benefits generated from its registration will accrue to all relevant communities.

The right provided by the registration of a collective right allows the holder of the right to prevent third parties from using and commercializing the object or knowledge without the consent of the indigenous congress or traditional authorities. The holder can prevent the reproduction, serigraphy or reproduction of the cultural object or feature. Registration of the right is for an undetermined period. Licences can be granted subject to consent and royalty payments.

Sanctions and penalties

Customs crimes – regarding merchandise imitating Panama indigenous peoples models – will be subject to a fine. The fine will be split equally between the national treasury and investment in the corresponding comarca). Fines vary from 1000 Balboas to 5000 Balboas² and can be doubled in cases of relapse. The Fiscal Code of Panama prohibits importation of non-original products (engraved, embroidered, textile) or other products that imitate traditional garments of indigenous peoples, as well as traditional musical instruments or traditional artwork of these people. Industrial reproduction of traditional dress is also prohibited – as established in Law No. 20 – unless otherwise authorized by the Ministry of Trade with the express consent of the general congress and councils of indigenous peoples.

² At the time of writing, the Panamanian balboa was approximately equal to the US dollar.

Box 3. ABS policies and legislation in Mexico

Mexico does not have a specific law on ABS. However, it has a very interesting experience with bioprospecting projects. Three recent experiences have shown varied degrees of success (and generated considerable controversy):

- Universidad Nacional Autónoma de México – Diversa, bioprospecting in extreme environments;
- UZACHI – Sandoz, bioprospecting on indigenous lands with no related TK;
- ICBG Maya, bioprospecting on indigenous lands with associated TK.

This is particularly in regards to the policy and social process concerning indigenous peoples' lands and territories.

The National Constitution refers to neither biological nor genetic resources in particular. The Law for Ecological Equilibrium defines genetic resources as "strategic resources" for Mexico. Article 87 of the Law regulates two types of situations: scientific collection (PIC is required from the owner of the land or property where resources are located, and research results must remain in the public domain); and biotechnology-oriented collection (benefit-sharing conditions must be agreed between the owner and the interested party). The Secretariat for the Environment, National Forest Commission and Secretariat of Agriculture all have competences over genetic resources.

NOM 126 – ECOL – 2000 established a requirement by which researchers must inform if objectives of research change (i.e. from scientific to biotechnological), with considerable limitations in terms of monitoring, given the jurisdictional issues and actual time when these changes may take place as part of the research process. The Forest Law has introduced some CBD principles (applicable to forest resources), including the need for PIC from owners of land, and benefit-sharing. A national policy for ABS is being developed and coordinated through the National Commission of Biodiversity (CONABIO). The main objectives of the national policy are to ensure respect for rights over genetic resources (including consideration of issues such as PIC, benefit-sharing, recognition of TK, innovations and practices), facilitate access to generate benefits, ensure research for scientific purposes, promote national biotechnological industries, reduce transaction costs of regulations, ensure synergies between international agreements, promote an international ABS regime, and acknowledge the importance of social processes and their impacts on the legislative process.

Conclusions

Costa Rica is the only Central American country with legislation (and regulations) in place specifically addressing access to and use of genetic resources and benefit-sharing. Most other countries apply their regular wildlife and scientific collecting permits regulations (even when access to genetic resources is sought). Legislation is mostly fragmented, sometimes overlapping and with contradictions.

All Central America countries recognize that genetic resources (through a reference to natural resources) are patrimony of the nation, and that the state exercises rights over them. At the same time, they recognize private property (or community property) rights over certain biodiversity components. This calls for a conceptually (and maybe legally) necessary – but in practice complicated – distinction between a set of rules and rights governing genetic resources and a set governing access to and the use of biological resources, which may contain them.

All countries have made progress in developing ABS policies. This has occurred through National Biodiversity Strategies or other planning instruments. All countries seem to have chosen the path of developing specific ABS laws and regulations rather than modifying or complementing existing legislation (i.e. on scientific collection of plant specimens). There are considerable differences among countries in the level of awareness regarding the key ABS policy and legal issues, especially at the level of public authorities.

Information regarding ABS projects is very fragmented and often hard to obtain. Except for the case of Costa Rica – mostly due to INBio's experiences and publicity of most of its projects – detailed data on bioprospecting projects in each country is limited. Informal

conversations seem to indicate that there are projects in the region that imply accessing its biological and genetic wealth.

Collecting activities by *ex situ* conservation centres and transfer of materials is mostly unregulated. No specific policies and rules on ABS for these centres have been developed, though the law in Costa Rica, and the Mesoamerican draft, include references to specific legal treatment for these centres.

Implementation of specific ABS measures cause generalized problems and concern. In the case of Costa Rica, for instance, there are considerable concerns regarding the impacts the newly enacted Executive Decree will have on the only “successful” example of an institution undertaking bioprospecting for over 10 years now (INBio). There is uncertainty whether the new legal framework will generate the necessary incentives to continue promoting bioprospecting or, in contrast, whether these activities (including those of INBio) may be negatively affected.

Most ABS policies, draft laws and law (in the case of Costa Rica) make specific references to indigenous peoples’ TK, innovations and practices and the need to protect them. Except for Panama (and to some extent general provisions in Law 7788 in Costa Rica), no country has yet developed specific laws or regulations on indigenous peoples’ TK. In the case of Panama, the law for the protection of TK does not relate exclusively to biodiversity and TK, but focuses on traditional expressions of the culture of indigenous peoples.

Countries, not highlighted in this report, have a wide range of laws and regulations that address genetic resources, though not necessarily in the context of ABS. Laws for conservation, forests, seed, phytosanitation, plant breeding, intellectual property and wildlife all address a particular aspect or issue related to the use of genetic resources.

There are no examples of specific bioprospecting projects or activities approved through the application of specific ABS laws and regulations. Most projects have been executed in the context of laws governing wildlife collecting permits, though CBD principles have been incorporated into the corresponding bioprospecting agreements and general biodiversity or ABS national policies. No concrete evidence has been found, but experts concur in recognizing that bioprospecting is taking place, sometimes bypassing laws and policies.

Quite clearly, Law 7788 (and its implementing Regulation), the draft Central America Agreement on ABS, and draft laws in the region have been to a considerable extent modelled on the content of Decision 391 of the Andean Community on a Common Regime on Access to Genetic Resources (1996). Concepts such as “framework access agreements” and distinctions between rights over genetic resources and biological resources, procedural aspects (access contracts, accessory contracts, publication of applications, defensive protection through the IPR system) indicate such an influence. One aspect to consider in this context is the very limited effectiveness that Decision 391 has had in the region, and the dangers or risks of modelling national approaches too much on existing examples, whether Decision 391 or others.

2. Costa Rica

Jorge Cabrera Medaglia

Legal considerations relating to genetic resources

The legal regimen of genetic resources in the country in private, public and indigenous lands

In Costa Rica, the genetic and biochemical resources are property of the state due to their being considered public goods. They are independent of owners of private lands, indigenous territories or property rights over the biological resources. PIC of the owners of indigenous territories, public or private owners of the lands or of the biological resources containing them is required to allow access, without granting them a right of property over the genetic and biochemical components. The law requires the applicant for access to attach PIC granted by the owner of the land where the activity will occur, by the authority of the indigenous community when it is in its territories, or the Director of the Area of Conservation (Article 65, Law of Biodiversity).

The Law of Biodiversity of Costa Rica, No 7788 of 27 May 1998, is applied to the components of biodiversity under the sovereignty of the state, as well as to the processes and activities carried out under its jurisdiction or control, independently of those effects manifested inside or outside of national jurisdiction. This law specifically regulates the use, management, associated knowledge and sharing of the benefits and derived costs of the use of the biodiversity components (Article 3). Also, Article 6 (public property), establishes that biochemical and genetic properties of the components of the wild or domesticated biodiversity are public property. The state can authorize exploration, research, bioprospecting and use of biodiversity components constituting part of public property, as well as the use of all genetic and biochemical resources, through access requirements established in Chapter V of the law. According to Articles 62 and 69, all research or bioprospecting programmes for genetic or biochemical biodiversity material require an access permit, unless excepted by this law. These exceptions (Article 4) basically refer to access to human genetic resources; the exchange of genetic and biochemical resources; and the traditional associated knowledge resulting from traditional practices of indigenous peoples and local communities. The non-profit and public universities had one year (up to 7 May 1999³) to establish their own controls and regulations for their research that implied need for access. All sectors (pharmaceutical, agricultural, crop protection, biotechnology, ornamental and herbal) wishing access to genetic components are subject to the law and should follow the specified procedures.

In this regard, the access regulations are applied to genetic resources on public or private lands, terrestrial or marine environments, under *ex situ* or *in situ* conditions and in indigenous territories.⁴ Relevant access provisions of the law are applied to indigenous territories, but additionally the customs of these peoples should be taken into account, as well as the *sui generis* community intellectual rights. Similarly, it is recognized that communities and indigenous peoples have the right to oppose access to their resources and associated knowledge, for cultural, spiritual, economic or other reasons.

³ Only the University of Costa Rica developed Regulation of Access

⁴ Article 2 (area of application) of the Draft Regulations on Access states that it shall be applied on genetic and biochemical elements of wild or domesticated biodiversity, *in situ* or *ex situ*, under state sovereignty, whether public or private property.

The Wildlife Conservation Law, No 7317 of 21 October 1992, declares public property the wild fauna and flora that constitute a renewable natural resource, which is part of the national heritage, including conservation, research and development of genetic resources, wild botanical and zoological species, breeds and varieties that constitute genetic reserves, as well as all wild species and varieties that have been modified genetically in their process of adaptation to several ecosystems (Article 3). The Ministry of Environment and Energy is involved in producing, managing, extracting, marketing, industrializing and using genetic material derived from wild flora and fauna, and their parts, products and by-products, which are declared public patrimony and national heritage. The ministry can authorize concessions for individuals, with the terms and conditions contributing to national interest through public letting and according to the provisions of the law and its regulation (Article 4). The implications for these standards due to the promulgation of the Law of Biodiversity will be discussed later.

The General Environmental Law regulates some aspects related to research on biological diversity. It establishes, in Article 46, that the state shall exercise its sovereignty over biological diversity, as a part of the natural heritage. Activities involve conserving, improving, recovering and using the biological diversity in the public interest.

Article 47 states that research, exploitation and marketing of biological diversity shall be recognized as activities of public interest. The exploitation and marketing of wild flora and fauna as goods of public property will be regulated by the state.⁵

The access system to genetic resources based on the Wildlife Conservation Law and its Regulation No 26435-MINAE of 3 December 1997, and permits for collection of wild flora and fauna (Article 36 *et seq.*) are granted by the 'Unique Window' of the National System of Conservation Areas or *Ventanilla Única del Sistema Nacional de Áreas de Conservación* (SINAC). This is after the application is completed and consultation completed with the Area of Conservation where the research and collection is planned. The procedure⁶ is relatively simple and it takes approximately 1 month to obtain the respective research permit⁷.

The Biodiversity Law entered into force in April 1998 (Article 117). However, there is a pending constitutional challenge submitted by the General Attorney's Office of the Republic for it to be properly accepted for discussion by the Constitutional Chamber (Action of Unconstitutionality No 98-006524-007-CO-M, accepted by Resolution of 8 October 1998). This action does not suspend the execution of the law in question (Law of Constitutional Jurisdiction No 7135 Articles 81 and 82), but, from a political point of view, it has delayed the effectiveness of the National Commission for the Management of Biodiversity (CONAGEBIO).

This action was presented against Articles 14 and 22 of the law. For access to genetic resources, Article 14 is critical. This establishes CONAGEBIO, which defines the national policies on biodiversity, including access to genetic resources. The chapters relating to access to genetic resources (procedure and substantial aspects) have not been discussed and for this reason, if declared pertinent, would only affect CONAGEBIO's powers, but not the rest of

⁵ The General Law on Environment requires that researchers submit a final report on environmental to the National Council of Science and Technology when they are carried out on or in state lands or institutions (Article 16).

⁶ Information required includes: researcher data, address, university or institution, description of the research project, site of activity, whether for collecting specimens or other materials, duration, goals, expected outcomes, source of funding, services requested in the area, and a declaration of non-commercial purpose.

⁷ Regulation No. 30355-MINAE, published in *La Gaceta* on 15 May 2002, called "Tariffs for Wild Protected Areas under Management of the National Conservation Area System", specifically stipulates that access permits are ruled by the Biodiversity Law (Article 20).

the applicable provisions. This power was considered unconstitutional by the Minister of the Environment and Energy, and the General Attorney's Office presented the request to declare it unconstitutional for the following reasons:

- CONAGEBIO's power to formulate and coordinate national policies (Subsections 1, 2, 3, 4 and 5 of Article 14) and that for using the administrative channel (*vía administrativa*) in case of appeals presented against the resolutions of the Technical Office of the Commission (Article 14.6), would violate the constitutional provision establishing that this power (formulation and coordination of policies) be exclusively for the Executive; and
- independent management of public funds (Articles 19 and 20 of the Law in relation to Article 14) conflicts with Articles 121, 176 and 180 of the Constitution.

This challenge has resulted in delaying many of the necessary decisions on the effectiveness of the law. CONAGEBIO was not operational until January 2000, almost two years after the law became operational. Equally, there is a legitimate fear that this challenge would be declared pertinent, with uncertain consequences. Hence, the role of CONAGEBIO may be modified to that of a consultative body rather than an executive decision-maker and developer of public policies.

The Technical Office in charge of approving the access applications is established. The publication of the General Access Standards to Genetic and Biochemical Components and Resources of Biodiversity in Article 62 of the Law of Biodiversity, to regulate access to genetic and biochemical elements and resources of biodiversity, is expected.

About the extent of the concept of goods of public property⁸

The Costa Rican legislation declares genetic and biochemical resources as goods of public property. Public property goods (belonging to a public body) are linked to public utility purposes. They are therefore subject to a special administrative regime of protection and use. Public property goods have three characteristics: ownership by a public body; a public utility purpose; and are under a special administrative regime of protection and use.

The public property reflects a high grade of public purposes that excludes all relationship of property. Thus, when speaking of public property, reference is made to a legal procedure that leads to an administrative title of intervention on goods, which must be considered as a *res extra commercium*, more than a special type of property. The state exercises a special protection based in the power (and competences) regulated by Public Law in guaranteeing the compliance of the purposes to which the goods are linked.

The notion of public property in the Costa Rican legal system reflects a non-patrimonial conception. Article 121.14 of the Constitution establishes that it corresponds to Legislative Assembly and shall decree the application to public uses of government property. That is, when the state in exercise of the legislative power, declares goods linked to public uses. At the same time, Article 261 of the Civil Code qualifies as public things (equivalent term to public goods) those having by law a general utility service and those linked to a public use. This Article states:

"Article 261. ...public things are those that, by law, are permanent aimed to any general utility service, and those that everybody can take advantage because are linked to the public use.

"All the other things are private or subject to private property, although they belong to the state or local administrations, who for this case, as natural people, don't differ of any other person".

The constitutional jurisprudence has qualified the goods of public property as *extra commercium* goods. Their destination is public use and for this reason they are subject to a

⁸ Statement of General Attorney's Office of the Republic No C-295-2001

special legal regime. In this respect, the Constitutional Chamber has repeatedly pointed out that:

"IV. (...) The public property is integrated by goods that manifest, by legislator's express will, a special destination of serving the community, the public interest. - they are called, goods or public things or public goods that don't belong individually to the owners and they are assigned to a public use and subject to a special regime, out of the trade. ...*Id est*, affected by its own nature and vocation (Constitutional Chamber of the Supreme Court of Justice. Award No. 2306-91 of 6 November 1991)."

Assignment consists on the destination that government attributes to some goods for the execution of a public purpose; *id est*, their destination for a public use or a service. The Constitutional Chamber, on the other hand, has defined assignment as:

"II. (...) Assignment is the fact or the manifestation of will of government, by which the thing is incorporated to the use and enjoyment of the community and it can be made by law or administrative act. The doctrine makes the distinction among 'earmarking of public nature' to one thing with the 'assignment' of that thing to the public property (Constitutional Chamber of the Supreme Court of Justice. Award No 3145-96 of 28 June 1996)."

In our legal system, and with conformity to the interpretation made by Constitutional Division, there is a non-patrimonial conception of goods of public property. The assignment is to a public use or utility.

There are goods that are out of the trade, non-susceptible of private appropriation, regarding which state shows an administrative title of intervention to guarantee their subjection to public purposes to whose satisfaction are aimed. This implies the application of a special legal system of Administrative Law implying the attribution of certain characteristics of this type of goods such as non-assignability, non-applicability, and immunity from seizure. Also, the application of this regime implies the use by the state of different means of guardianship and protection to those that the owner can use. This has been pointed out by Constitutional Chamber when, in the award mentioned *supra*, states that:

"IV. (...) Characteristics of these goods, are non-assignability, non-applicability, immunity from seizure, they cannot be mortgaged neither to be susceptible of obligation in terms of Civil Law and the administrative action substitutes to the injunctions for recover the property. ...since they are out of the trade, these goods cannot be subject to possession, although a utilization right can be acquired, although not a property right (Constitutional Chamber of the Supreme Court of Justice. Award No 2306-91 of November 6 1991)."

However, it is necessary to clarify that the concept of sovereignty is different to that of patrimony and to that of property. The latter is not dealt with in the CBD, leaving to each state the freedom to decide whether genetic resources are private or public property, and under what circumstances. The concept of public property in Costa Rica has been broadly analyzed by the Constitutional Division and the General Attorney's Office of the Republic and, in general, it has the nature indicated earlier. Public property implies that resources in its entirety possess those characteristics mentioned earlier, but in case the resources have been delivered by an appropriate legal mechanism (concession or permit), the holder has a right of property, except in the case that authorizing title stipulates otherwise. Fauna, for example, is public property, but the hunting and fishing permits allow its more complete appropriation, including its destruction. Also, the concessions for water, minerals and hydrocarbons confer a property right, allowing the minerals, water or hydrocarbons to be sold, given, granted or destroyed. The non-assignability, non-applicability and immunity from seizure of the resources of public property should apply to petroleum, gold or water, not to the resource that has been authorized to be appropriate. This subject will be developed later on.

Additionally to the policy sources mentioned, basically the nature of goods of public property has been interpreted deriving from the existing constitutional norms.⁹

Indigenous territories¹⁰

Indigenous Law No. 6172 of 16 November 1977 establishes that indigenous communities have full legal capacity to acquire rights and contract all kind of obligations (Article 2). Reserves mentioned in Article 1 of the Law are declared the ownership of the indigenous communities (Article 2). The Indigenous Reserves are non-assignable, non-applicable, non-transferable and exclusive of the natives that inhabit them. Non-indigenous entities would not be able to rent, lease, buy or in any other form to acquire lands or properties within these reserves. Any transfer, negotiation or improvements of lands among those not indigenous and the indigenous are considered absolutely null (Article 3). Reserves are managed by indigenous in their traditional community structures or by the laws of the republic that govern them under the coordination and consultation of the National Commission on Indigenous Affairs (CONAI). Indigenous populations of each reserve constitute a single community managed by a Principal Council (Article 4). Regarding those considered indigenous and belonging to the communities, the Constitutional Division has pointed out that the same autochthonous communities define their own members by applying their own approaches. Therefore these approaches and procedures should be respected in considering a person to be a member of an indigenous community (Constitutional Chamber Vote No 1786-93 at 16:21 on 21 April 1993).

The regulation implementing the Indigenous Law, Decree No. 8487-G, establishes that to exercise the rights and execute the obligations referred to in Article 2 of the Law, the indigenous communities shall adopt the organization expected in Law No. 3859 of the National Direction of Associations of Communal Development. From a legal point of view, land ownership then corresponds to the Development Integral Indigenous Associations (DIIA).

Ownership in indigenous territories has been considered as an exception to the right of collective property in our country. It is a right of special ownership, created to define the role of the state in front of that right, to protect a historic reality (Agrarian Court of Limón, Resolution No. 53-93 at 8:00 on 13 October 1993). Given its non-assignable nature, it is not possible to recover ownership (First Chamber Award No. 223 at 15:30 on 6 July 1990).

Only those with indigenous status will be able to build houses, cut down trees, exploit timber resources or grow crops for their profit within reserve limits. Mineral subsurface resources are the heritage of the state and the indigenous communities, and new permits or renewals of existing ones for exploration and mining exploitation shall require authorization of CONAI (Article 6).

Forest lands within reserves shall keep retain that nature in order to maintain hydrological balance in basins and support wildlife (Article 7). Renewable natural resources should be exploited rationally. Forest projects only can be carried out by state institutions that guarantee renewal of the resources, under authorization and permanent surveillance of CONAI. CONAI shall be specifically authorized to revoke or suspend at any time the conferred permits when there is either an exploitation abuse or danger to the regional ecological balance (Article 7). DIIA, in coordination with CONAI, shall be responsible for territorial demarcation of the Indigenous Reserves (Article 8).

⁹ Cf. Cabrera 1994 *Sobre el regimen constitucional de la diversidad biológica* [On the Constitutional System for Biological Diversity].

¹⁰ Although the objective of this consultant is to define legal situation related to genetic resources, in the case of indigenous lands it is essential to realize some references to the land right issue.

At the same time, according to Article 15 of the regulations, CONAI and DIHA shall coordinate at ministerial and other local entity levels the application of preventive and repressive actions to preserve the archaeological, mineral, hydrological, forestal and faunal heritage of all reserves.

In accordance with Convention No. 169 of the International Labour Organization (ILO) on Indigenous and Tribal Peoples in Independent Countries, indigenous and tribal peoples shall enjoy the full measure of human rights and fundamental freedoms, without hindrance or discrimination (Article 3). Also, it states that special measures shall be adopted as appropriate for safeguarding the persons, institutions, property, labour, cultures and environment of the peoples concerned. Such measures should not be contrary to the freely expressed wishes of the peoples concerned (Article 4).

Article 6 imposes on the governments the obligation to "Consult the peoples concerned, through appropriate procedures and in particular through their representative institutions, whenever consideration is being given to legislative or administrative measures which may affect them directly". Article 7 states that the peoples concerned shall have the right to decide their own priorities for the process of development, as it affects their lives, beliefs, institutions and spiritual well-being and the lands they occupy or otherwise use, and to exercise control, to the extent possible, over their own economic, social and cultural development.

Article 14 forces governments to take steps as necessary to identify the lands that the peoples concerned traditionally occupy, and to guarantee effective protection of their rights of ownership and possession.

Article 8 specifies that when applying national laws to the peoples concerned, due regard shall be given to their customs or customary laws, and Article 15 establishes that the rights of the peoples concerned to the natural resources pertaining to their lands shall be specially safeguarded. These rights include the right of these peoples to participate in the use, management and conservation of these resources. In cases in which the state retains the ownership of mineral or subsurface resources or rights to other resources pertaining to lands, governments shall establish or maintain procedures through which they shall consult these peoples, with a view to ascertaining whether and to what degree their interests would be prejudiced, before undertaking or permitting any programmes for the exploration or exploitation of such resources pertaining to their lands. The peoples concerned shall wherever possible participate in the benefits of such activities, and shall receive fair compensation for any damages that they might sustain as a result of such activities.

These obligations should be complied with by public authorities and they are relevant when analyzing legal regulations that can be issued for governing the utilization of natural resources in indigenous territories, including for projects or activities that can be carried out in these territories with the purpose of contributing to the development and use of the resources by indigenous peoples.

The norms of ILO Convention 169 are considered an integral part of the International Law for Human Rights, and they are binding since they embody fundamental rights of indigenous peoples (Constitutional Chamber Vote No. 8019 at 10:18 on 8 September 2000, and also see in general Vote No. 5569-00 at 9:04 on 7 July 2000).

Definition of genetic resources

The Biodiversity Law does not define the term "genetic resources". Article 7 of the law, Subsection 14, defines genetic elements as any material of plants, animals, fungi or microscopic organisms containing functional units of inheritance. Subsection 13 of this Article defines biochemical element as any material derived from plants, animals, fungi or

microscopic organisms containing specific characteristics, special molecules or traces to design them.

However, the term “access” is defined in Subsection 1 of Article 7 of the Law of Biodiversity as the action of obtaining samples of elements of wild or domesticated biodiversity, under *ex situ* or *in situ* conditions, and obtaining associated knowledge, for basic research, bioprospecting or economic utilization purposes. Also, the Draft Regulations on Access (Article 6) defines three elements:

- **Organic resource** — Any material of live, wild or domesticated, organisms used as such, in its entirety or in its macroscopic parts.
- **Biochemical resource** — Any material derived from living organisms, searched or used by its current or potential value that possesses certain specific characteristics, special molecules or traces to design them. Unlike organic use of resources, the biochemical resource suffers a bigger transformation and technical-industrial utilization, and it has in general a greater number of active ingredients.
- **Genetic resource** — Any material of living organisms that contains functional units of inheritance and is managed and conventionally innovated by farmers and plant or animal breeders, or used in modern biotechnological procedures, with current or potential value.

Relevant international legal obligations

Relevant conventions relating to genetic resources and ratified by Costa Rica

The international legal obligations ratified by Costa Rica are listed in Table 2.1.

Table 2.1 Conventions and agreements, and when ratified by Costa Rica.

Conventions and agreements	Ratification/Accession
Convention for the Protection of the Flora, Fauna and Natural Scenic Beauties of the Countries of America (Washington Convention).	12 February 1966
International Plant Protection Convention (IPPC)	23 July 1973
Convention establishing International Regional Plant Health Organization (ORPHO)	20 June 1991, Law No. 7231
Convention establishing World Intellectual Property Organization (WIPO)	10 June 1981
Convention 169 of International Labour Organization (ILO) on Indigenous and Tribal Peoples	4 December 1992, No. 7316
Convention on Biological Diversity, Río de Janeiro 1992	Law No 7416 of 26 August 1994
Convention for Conservation of Biodiversity and Priority Wild Areas Protection in Central America	11 October 1994, Law No. 7433
Marrakesh Agreement establishing the World Trade Organization (WTO)	Law No 7475 of 20 December 1994
Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES)	Law No. 5605 published in La Gaceta on 28 January 1975
Central American Convention for the Management and Conservation of Natural Forest Ecosystems and the Development of Forest Plantations	Law No 7572 of 6 March 1996
International Treaty on Plant Genetic Resources for Food and Agriculture (ITFGRFA)	Signed. Text published in La Gaceta on 24 September 2003
Paris Convention for the Protection of Industrial Property	31 October 1995
Patent Cooperation Treaty (PCT)	3 August 1999
Cartagena Biosafety Protocol	Signed. Text published in La Gaceta on 3 July 2002

Provisions applicable to the protection of traditional knowledge and farmers' rights¹¹

Several aspects were taken into account with regard to TK protection. The problems in applying existing mechanisms for the protection of knowledge, innovations and practices have been presented in studies from several points of view. Some initiatives for use of traditional mechanisms related to intellectual property have been outlined, such as geographical indications and origin denominations, collective marks, copyright and related issues, trade secrets, patents and plant breeders' rights. However, there are contentions, and a development of *sui generis* schemes of protection is needed. Some concrete proposals have already been presented on this subject.

Costa Rica's protection system for TK is based on several premises, namely:

- The legal system of access assures PIC and the sharing of benefits from TK, and the Technical Office, and eventually the National Commission of Biodiversity, have control, authorization and revision powers (Articles 63, 65, 66, 72, *inter alia*). From this point of view, it is a compromise between access mechanisms, contracts or licences, and a *sui generis* scheme based on registers.
- There exist valid forms of knowledge and innovation that need to be protected through the use of appropriate mechanisms (Articles 77), such as patents, trade secrets, copyright, plant breeder rights, community *sui generis* intellectual rights, *inter alia* (Article 78).
- Legislation is aimed at protecting knowledge through a registration system, a topic that has been supported by doctrine. Thus, it should inventory community *sui generis* intellectual rights for which the communities request protection (Article 84). Nevertheless, these registration systems have been criticized because of the problems that they pose. Points of contention include the need to define access to information; its control; and the possibility that communities not involved in access grant the prior consent for knowledge registered on behalf of others.
- A consultation process should begin with indigenous and farmer communities on the definition of the extent, nature and requirements of these rights (Article 83 of Law of Biodiversity). The process will determine how the community intellectual right will be used and who will exercise ownership, and identify the target groups that will benefit (Article 85).
- The following will be considered for the assigning of rights and obligations, whether collective or private:
 - **Material to be protected:** this is the knowledge, innovations and practices of local communities and indigenous peoples; these terms are not defined. They are those associated with genetic and biochemical elements (Article 82) and include knowledge of medicine or agriculture, but excludes folklore. In contrast, Panamanian law primarily regulates folklore. Possibilities of regulation for sectors (medicine, etc.) developed in a progressive form should be analyzed. However, some aspects should still be defined, such as requirements to identify material to be liable to protection, and the power of the entity in charge of registration (in this case the Technical Office of the Commission, Article 84). The risk is to assign more than necessary to public property, create speculative claims and, in general, become insensitive to the extent of the rights and the obligations of third parties and actions contravening agreed rights. Obviously, some characteristics of these rights, such as evolution and adaptability, should be recognized in order to incorporate flexibility in the registration system.

¹¹ See *El sistema sui generis para la protección de los conocimientos tradicionales: un estudio de la Ley de Biodiversidad de Costa Rica y normativa relacionada*. Jorge Cabrera Medaglia. Document submitted to Informal Panel of WIPO on national experiences about sui generis systems of protection. Geneva, 9 July 2003.

- **The registration procedure:** in Costa Rica, this procedure is voluntary and declaratory, free, unofficial, informal and without a time limit. Other elements should be indicated, such as the possibility of opposition, existence of expert examiner of the topic, reciprocity in recognizing the right of other countries, reasons for revocation and nullification, and appeals modalities. Relationship between this protection and other protection through the traditional IPR scheme should be recognized (e.g. trade marks and geographical indications).
- **Granted rights:** the Costa Rican Law is very precise on this topic and several provisions can be noted: impossibility of granting IPRs in the resources; the need for PIC and for MAT for benefits in case of access and use; and the right of cultural objection on religious grounds. In general, rights derived from the existence of community intellectual *sui generis* rights should be defined. This topic is very important, since it should define the extent of the right and its limitations, *id est* terms, loss and binding licences. Being community rights, they cannot be an exception to modalities mentioned earlier. Another point to regulate is the collective versus private nature of knowledge. The law states its communal nature, but this does not necessarily imply it cannot be private. In that sense, especially in local communities, the supposition that all knowledge is generated in collective form is difficult to support.
- **Observance of and compliance with rights:** protection regulations will be insufficient without substantive mechanisms for observance of the rights. The Costa Rican Law has not addressed this subject sufficiently; it just stipulates this through the requirements of presenting the "origin certificate", approval of IPRs, and obligatory consultation with the Technical Office of CONAGEBIO on IPR applications that use resources or knowledge. More provisions on civil and penal sanctions and administrative measures are provided for in Venezuelan and Panama Laws.

The success of the expected scheme will depend greatly on the existence of regulation and the consultation process effect on the extent of rights. There is a finished document as a result of the consultation process, basically referring to access procedures to TK.

Provisions of access and distribution of benefits

Specific policies, laws and regulations to regulate access to genetic resources

In Costa Rica, there are no specific laws or regulations for access to genetic resources, but regulation is addressed in Chapter V of the Law of Biodiversity. A National Strategy of Biodiversity establishes a number of actions to be taken for access to genetic resources. Also, there is a National Strategy of Research of the National System of Conservation Areas of Ministry of Environment, which would be applicable to research implying access to genetic resources by officials of the ministry, such as joint research between them and other organizations or entities.

In accordance with Article 62 of Law of Biodiversity, the competent organ for access to genetic and biochemical resources, CONAGEBIO, developed "Access Norms" that establish access procedures to these resources. The publication and entry into force of these standards were still pending at the time of writing.

Existing institutional framework for regulating access

Law of Biodiversity establishes CONAGEBIO, with instrumental legal staff and as a decentralized organ of the Ministry of Environment and Energy (Article 14). It is to: (a) develop policies and responsibilities set up in Chapters IV, V (Access to genetic and biochemical elements and protection of associated knowledge) and VI of the law; (b) coordinate them with several responsible organisms on these subjects (Subsection 2); and

(c) formulate and coordinate policies for access to biodiversity element-associated knowledge. This should ensure adequate scientific and technical transfer and fair sharing of benefits, and for Chapter V purposes, this law will be denominated “General Access Norms” (Subsection 3). The commission shall implement its agreements and resolutions and institute its procedures through the Executive Director of the Technical Office (Article 16). This entity is formed by government entities, including the Ministry of Environment (President), Ministry of Foreign Trade, Ministry of Health, Ministry of Agriculture, Costa Rican Institute of Fishing and Aquaculture, National Commission of Rectors, Indigenous Table, Farmers Table, National Union of Cameras, Costa Rican Federation for Conservation of the Environment, and the National System of Areas of Conservation Director (Article 15).

This commission shall formulate policies on access and distribution of benefits and can revoke Technical Office resolutions on this subject (Article 14).

In accordance with Article 62, CONAGEBIO shall propose access policies for genetic and biochemical elements of biodiversity *ex situ* and *in situ*, and act as binding consultative organ in concerning requests for IPR protection on biodiversity.

The commission has a Technical Office for support, formed by an Executive Director and the staff indicated in the Regulations. The Technical Office will: process, reject or accept, and control access applications to resources of biodiversity (Article 17a); coordinate all access with Conservation Areas, private sector, indigenous peoples and local communities (Article 17b); organize and maintain an updated register of access applications to biodiversity elements, *ex situ* collections and those from natural and juridical persons dedicated to genetic manipulation (Article 17c); and gather and update regulation relative to compliance of agreements and guidelines on biodiversity (Article 17d).

Actions of the commission have been regulated by Decree No. 29680 MINAE published in *La Gaceta* on 7 August 2001, and their members designated by Decree 29476-MINAE of 17 May 2001, with a term of membership of two years. The last integration of the commission was established by Decree No. 31126-MINAE published in *La Gaceta* on 2 May 2003.

Main contents of existing regulations relevant to ABS for genetic and biochemical resources

The Biodiversity Law establishes the basis for access permits and contracts and contains definitions on such crucial topics as access to biochemical and genetic elements, bioprospecting, PIC, biochemical and genetic element, innovation and access permit (Article 7). It defines the application of access procedures and resolves existing doubts in the matter. Thus, the research purpose is to elaborate an inventory or a taxonomic description. It is an activity out of the access and regulated by a separate legal body, the Wildlife Conservation Law (particularly Article 36 *et seq.*). Also, it clarifies the ownership of genetic and biochemical resources of wild or domesticated biodiversity, declaring them public property (Article 6). It clarifies that they belong to the state as manager; hence two different properties are separated: biological or organic resources, and genetic and biochemical resources.

The access procedure is regulated in detail in the law. The competent organ to grant access is the Technical Office of CONAGEBIO. In Chapter V, Section I, requirements and procedures for access to genetic and biochemical elements and protection of associated knowledge are defined. The commission is to propose access policies on genetic and biochemical biodiversity elements *ex situ* and *in situ*, and will act as binding consultative organ in procedures for requesting IPR protection on biodiversity (Article 62). The law regulates basic requirements for access that include PIC, distribution of benefits, protection of associated knowledge, and the way in which activities will contribute to conservation (Article 63). It establishes the procedure to be followed (Article 64), cultural objection right

(Article 66) and register of access applications and protection of confidential information (Article 67). In Section II, the law regulates in more detail the topic of permits for research and bioprospecting (Article 69), their terms, limitations and characteristics (Articles 70–71); requirements for access application (Article 72); Technical Office authorization for those agreements subscribed among individuals that provide for access to genetic and biochemical elements (Article 74); and possibility of framework contracts with duly registered universities and other centres (Article 74). It establishes that up to 10% of research budgets and 50% of royalties are for favour of the Area of Conservation, private ownership or indigenous land, as well as the administrative costs (Article 76).

Section III addresses the limits of property rights (Article 78) and suitability of these rights for conserving biodiversity (Article 79). In all the cases, Technical Office must be consulted in the process of grants on IPRs on biodiversity elements (Article 80).

Lastly, the law establishes the basis for protection of traditional indigenous and local knowledge and for the beginning of a participatory process for determination and registration of these intellectual community *sui generis* rights (Articles 82 *et seq.*). A system of fines for illegal access is established as part of the penalty framework (Article 112).

Other policies, laws and regulations with potential impact (direct or indirect) on access and distribution of benefits

Wildlife Conservation Law and Regulation

The law declares of public interest wild flora conservation, research and development of genetic resources, species, breeds and wild botanical and zoological varieties that constitute genetic reserves, as well as all wild species and varieties that have suffered genetic modifications in their process of adaptation to several ecosystems (Article 3). The production, management, extraction, marketing, industrialization and use of genetic material of wild flora and fauna, their parts, their products and by-products, are declared of public interest and national heritage. This law also regulates scientific or cultural collecting and wild flora and fauna research (Articles 36 *et seq.*), as well as the extraction and gathering of wild flora. Previous to the Biodiversity Law, this law empowered the Technical Unit of Support of the General Direction of Wildlife (SINAC) to authorize permits for the bioprospecting.

In general, gathering and research activities on biological diversity are regulated by Wildlife Conservation Law (Articles 36 *et seq.*), through the Regulation of Investigations in National Parks Decree 12329 - A of 1981, in Forest Law (Articles 1 and 18) and its Regulation. Other provisions are applicable. The Convention for the Protection of Flora, Fauna and Natural Scenic Beauties of the Countries of America, Article 3, establishes that contracting governments agree that national parks would not be altered, cannot be sold or in whole or in part except by competent legislative authority action. The existing natural wealth in them must not be exploited for commercial purposes.

Contracting governments agree to prohibit the hunting, slaughter and capture of fauna specimens and destruction and gathering of flora samples in national parks, except when it is made by authorities of the park or by order or under the surveillance of these, or for properly authorized scientific investigation purposes.

In accordance with Article 6 of the Wildlife Conservation Law, the General Direction of Wildlife of the Ministry of Environment and Energy (GDW; its functions are exercised by the SINAC) is the competent organ for the planning, development and control of wild flora and fauna.

Amongst their more relevant functions (Article 6) are to:

- establish technical measures to be followed for good management, conservation and administration of wild flora and fauna, under this law and the respective conventions and international treaties ratified by Costa Rica; and
- grant or refuse hunting permits, continental or insular fishing, flora extraction and any permit to import or export wild flora or fauna.

SINAC can consult with other entities on applications for wild flora gathering when it does not have the suitable staff to process them (Article 8 of Regulation of Law of Wild Conservation). It will consult with other scientific entities linked with biological diversity: the National Museum, University of Costa Rica, National University, Technological Institute of Costa Rica, and other public or private entities considered suitable.

Part of the generic regulations on permits are further considered below, in the section related to gathering. Nevertheless, provision of Article 17 is relevant, because it states that Ministry of Natural Resources, Energy and Mines is empowered to grant contracts, use rights, licences, concessions or any other legally established legal step for conservation and sustainable use of the wildlife.

This norm grant SINAC various powers of diverse nature, that can include contracts or general agreements relating to collection and inventory activities. SINAC will be able to grant concessions for production, management, extraction, marketing, industrialization and use of genetic material of wild flora and fauna, using either bidding procedures (Article 4) or those specified in Article 17, with the following conditions:

- The beneficiary shall send annual technical reports on the activity, when required by SINAC.
- The beneficiary should allow officials from SINAC free access to the projects.
- Any beneficiary who does not comply will be served with a cancellation of the concession, as the execution of a compliance guarantee, with collection of any loss or damages (Article 26 of the Regulation). Award will only be made if a real and evident benefit is guaranteed for the state (Article 26, *op cit.*).

Standards related to the exercise of scientific or cultural gathering are in Article 36 of the law, which states that Costa Ricans and foreigners are authorized to carry out scientific or cultural collection of animals and plants, their products or by-products and to carry out researches, provided they do not contravene this law and its regulation.

Licences are granted by SINAC, on application in writing (Article 38) and in consultation with the relevant scientific authorities (Article 22 of the Regulation). Extraction and gathering of flora is classified as:

- scientific, if it is carried out for study or teaching purposes;
- commercial, if it is carried out for reproduction in nurseries or commercial purposes according to regulation of this law; or
- subsistence resources, if it is carried out to meet nutritional or medicinal needs of people of scarce economic resources, proven through standards provided for in the regulation of this law.

The duration will be a maximum period of 1 year for nationals or residents, and 6 months for foreigners. The licence can be cancelled by SINAC if the holder contravenes the law or its regulation, or when use is considered inconsistent with national interest (Article 39 of the Law of Conservation).

SINAC shall maintain a register of the research and collections related to national wildlife. Research developed either in the universities and public or private institutions of the country, or those that are carried out in any foreign institution, will be noted. All scientists or researchers must submit annual or quarterly reports to the SINAC on the state of their

projects and findings. The institutional holder of an institutional project will be responsible for the research activities (Article 52 of the Regulation). Additionally, scientific or cultural institutions that carry out work in the Law of Wildlife context should request their inclusion in the Flora and Fauna Register, committing themselves to sending specific information to SINAC (Article 51 of the regulation).

Conditions to grant extraction and scientific gathering of wild flora licences for study or teaching purposes are specified in the regulation (Article 27). Requirements that should be met for registration of research projects implying some type of management of wildlife are established and are as follows: “request and complete the inscription form of researches prepared by SINAC for the purpose, be available in the *ventanilla única* of SINAC services; and present original and copy of the research project and support letter of the institution that supports researcher”. According to Article 51 of the law, licences for extraction and scientific gathering of wild flora for study and investigation purposes can be granted for development of educational programmes in the centres of primary and diversified teaching, recognized by the Ministry of Public Education and for the development of educational programmes in public or private higher education centres or scientific institutions properly accredited with SINAC (Article 28). Article 30 establishes some additional requirements.

Scientific or cultural wild flora and fauna gathering can be carried out in official areas of protection, with the written permit of the institution that manages them, and in private property lands, with the permit of whomsoever is legally authorized to grant such permission. Special requirements are specified in the regulation for obtaining licences of the commercial type, and highlights that it should have the permit of the owner of the land or certification of ownership. This standard seems to indicate that commercial gathering is allowed in non-official areas of conservation (Article 29 of the regulation). Article 56 of the regulation allows the scientific or cultural gathering —not commercial— of wildlife in wild areas property of the state, previous to obtaining a clearance of the respective Conservation Area, which will be responsible for the surveillance and supervision of the gathering (Article 56).

It is necessary to get written permission from SINAC in accordance with the law for export of specimens obtained through scientific or cultural gathering. When export corresponds to species contemplated in CITES Appendixes or species with populations protected locally under ‘sustained’ reproduction, it should have the respective CITES permits.

Besides phytosanitary certificates and other requirements specified by related laws, all exporters of native flora, its products and by-products should have a permit granted by SINAC. It should correspond to that provided in the international conventions ratified by the state (Article 55 of the Wildlife Conservation Law). The regulation also specifies standards related to flora and fauna export coming from scientific collection. It declares that the product must not be marketed (Article 36), and in the case of species included in CITES, there are specific procedures (Article 39).

It takes 1 month to process applications for permits to export, import and transit wild species (Article 40 of the regulation). Export permits for a single specimen, obtained through scientific or cultural collection, will be granted previous to consultation with the Advisory Committee of Wildlife or specialists in this subject. They will determine if the specimen or specimens, once classified, come out freely or in quality of lending, according to national interest.

In the same way, if specimens obtained through scientific or cultural collection are destined for foreign institutions, SINAC shall require, before granting the export permit for scientific or cultural purposes, the deposit of subsamples of the specimens, only and exclusively, for the National Museum and the University of Costa Rica (Law No. 4594 on 2 July 1970), and the botanical gardens and the state zoos (Article 46).

Legislation regulates charges associated with activities, with periodic updating. Decree No. 30343-MINAE published in *La Gaceta* on 15 May 2002 establishes a scale of charges for activities specified in Articles 34, 38, 53 and 64 of the Wildlife Conservation Law).

In principle, these provisions will be only applicable to the gathering of samples that do not involve access to genetic resources, but if access to organic resource is involved, these provisions should be applied. As has been affirmed (Wo Ching, 2002):

“Integrating to this interpretation the concepts of the Law of Biodiversity, we should understand that flora and fauna extracted or gathered, are in their physical or organic environment, and that neither species, nor their products or by-products, are referred to under the scope of this law, to the genetic or biochemical resources.

“When promulgating this law, there were no provisions on access, neither the Convention of Biological Diversity had been approved, for this reason. However, it contains provisions on genetic resources, which should be considered tacitly repealed from the entry into force of the Law of Biodiversity. In legal terms, two interpretation rules affirm that:

- a. “the Law of Biodiversity, although wider in its regulation of the three biodiversity components, is absolutely specific as regards access. However, some of its provisions are similar to those of Wildlife Conservation Law, which being more recent, supersede its provisions.
- b. “the Wildlife Conservation Law contravenes that provided in the Convention of Biological Diversity, because it does not establish provisions that make applicable the PIC, the fair and equitable distribution of benefits derived of the access, neither with respect to access and transference of technology, nor basic principles in the context of the CBD.”

Law on Phytosanitary Protection

The Law on Phytosanitary Protection declares that plant health is of public interest and establishes the application of phytosanitary measures (Article 1). The objectives of the law (Article 2) are to: protect plants from the damages caused by pests; avoid and foresee the introduction and spread of pests; regulate the control of these; promote integrated management within sustainable development; regulate the use of chemical, biological or related substances, and agrochemicals and equipment in agriculture, as well as their registration, import, quality and residuals to protect the environment and health; and ensure that these measures do not constitute an unnecessary obstacle to international trade. The law assigns administrative responsibility to the Ministry of Agriculture and Livestock (MAG) (Article 5). The following elements also have an impact on access to genetic resources and on sharing of benefits: looking after the health and protection of plants; preparing and executing technical, legal and administrative measures to avoid, foresee and delay the introducing and establishing of pests; collaborating in the issuing of legal standards and executing and diffusing the Regulations of the Law; effecting phytosanitary control of national and international plant exchange and agents of biological control and other types of organisms used in agriculture; controlling the phytosanitary quality of plant export; the use of transgenic material and other genetically modified organisms and their products; and promoting and supporting scientific research and the international harmonization of phytosanitary measures. Chapter V deals with the limits for elaborating, applying and observing phytosanitary measures.

Article 45 on evaluation of risks establishes that phytosanitary measures should be based on an appropriate evaluation of the existing risks for life and health of people or protection of plants, and reflect the evaluation techniques of relevant international organizations. It also states that as regards procedures of verification control and insurance of the execution of phytosanitary measures, the State Phytosanitary Service shall apply international conventions signed by Costa Rica in this matter, and in particular the procedures for control, inspection and approval in Annex C of the Agreement on Sanitary and Phytosanitary Measures of the Uruguay Round Final Act, Law No 7475 of 20 December 1994 (Article 47).

In Chapter VI, Section II, the phytosanitary regulation of biotechnological organisms or products establishes the Technical Commission on Biosafety (Article 40). Natural or juridical people who import, research, export, experiment, mobilize, liberate to the environment, multiply or market transgenic plants, genetically modified organisms or their products, agents of biological control and other types of organisms for agricultural use, produced inside or outside the country, must obtain the authorization of the Phytosanitary Service (Article 41). It establishes that permits can be revoked in the event of non-compliance. The Biodiversity Law repeats the provisions of the Law of Phytosanitary Protection; it extends the scope to exotic species and establishes CONAGEBIO's power to revoke permits, and requires Technical Office registration of those who carry out genetic manipulation.

Regulation of the Law of Phytosanitary Protection, Decree No 26921-MAG on 22 May 1998, states (about species protected under CITES) in Article 227, that the export of plants of the species in danger of extinction will be allowed once the documents required by the authorities of CITES are presented at the exit point. Article 228 determines that samples of plants or soil shipped abroad for research or physico-chemical laboratory analysis, should meet national phytosanitary requirements. These should be presented at the exit point in their respective packaging for inspection or authorization, and, if necessary, a phytosanitary certificate or authorization will be issued.

CITES regulations and other permits for export of wild fauna and flora

Decree No 31237 MINAE, published in *La Gaceta* No. 130 on 8 July 2003, establishes the administrative authority for application of CITES to be the National System of Conservation Areas, which will designate by agreement the representatives of the administrative authorities in flora and fauna. The Wildlife Conservation Law states in Article 71 that the government shall nominate one or several administrative authorities, whose main function would be granting export and import permits and certificates of origin. The decree regulates in detail functions of the administrative authority. There is one authority for flora and another for wild fauna.

Expressly, the Regulation of Wildlife Conservation Law states that the functions of SINAC are, *inter alia*, to authorize import and export permits for wild flora and fauna, as well as species included in the various CITES appendixes. The procedure in practice is carried out through the Unique Window (*Ventanilla de Atención al Usuario o Ventanilla Única*) of SINAC. Also, the General Director is empowered to supervise the correct application of laws and different international conventions on wildlife.

The law establishes that the government shall be able to nominate one or several scientific authorities whose function will be provide scientific information required for granting of permits or import and export certificates of wild flora and fauna. In Decree 31237, mentioned earlier, scientific authorities are nominated, independent and are from several scientific and academic institutions, including the National Museum, University of Costa Rica (School of Biology, Lankaster Garden and Clodomiro Picado Institute), National University (School of Veterinary Science, Biological Sciences and the System of Postgraduate Studies), Technological Institute (Department of Forest Engineering), School of Biologists, and Botanical and Simón Bolívar Zoological Garden. Their functions are defined in the same decree, and the Council of Representatives of the Scientific Authorities is established.

Costa Rica has specific provisions in its Wildlife Conservation Law related to CITES. It is forbidden to import and export fauna and flora included in Appendixes I, II and III of CITES, when the scientific authority advises that export or import will be made in detriment of the national wild flora and fauna. Export permits will only be issued for species included in Appendix II of CITES provided they were animal or plants artificially reproduced or with scientific or cultural purposes. It is forbidden to move, export or import fauna and flora, their

products and by-products, between states that are non-members of CITES. Moreover, all movement throughout the national territory should have the respective permits.

SINAC grants export permits for species reproduced in breeding farms or nurseries, registered according to the law. These permits are transferable. A SINAC permit is also required for specimens obtained by scientific or cultural collection. SINAC will grant export permits for wild flora with commercial purposes; CITES species should have the appropriate certificates. To grant export permits for species included in CITES, a rate of 10% of the CIF value for animals and 5% for plants should be paid, exclusively for the financing of the local structure of the convention to a Fund for Wildlife; this does not happen.

Regulation of the law establishes in detail requirements for wildlife import; export of wildlife species born in zoos, breeder units, aquariums and nurseries; wild flora and fauna export derived from scientific collection licences; export of species included in CITES; international movements; and import of exotic species. Also, there are Decree 27654-MINAE of 29 January 1999, "Procedure for import and export of wild fauna and flora species" and Decree 27639 MINAE of 15 December 1998 and its revision, called, "Quotas for internal trade and export of wild animals born in captivity and annual quotas of by-products".

In accordance with Article 31, the application to obtain an export permit for wildlife species born in zoos, breeder units, aquariums and nurseries requires:

- completing the requisite form;
- meeting CITES requirements;
- providing receipt of payment for the corresponding amount in accordance with Articles 26 and 57 of the LCVS, repealed by Law of Simplification and Tributary Efficiency, Article 31; and
- meeting of the international norms for the transporting of animals.

Applications for export permits of wild fauna and flora species born in breeder units, nurseries, zoos and aquariums will require the supervision of SINAC. They can be granted by the Administrative Authority without technical recommendation of the Scientific Authorities (Article 4). The Administrative Authority will have 30 working days to resolve the import or export applications of species included in the CITES appendixes (Article 5).

The user should meet the following requirements for granting export permit for species included in the appendixes of CITES (Article 39):

- complete the requisite form;
- pay the charge provided in Article 81 of the LCVS;
- present the clearance of CITES scientific authority as required by the administrative authority; and
- demonstrate that the species has been reproduced in nurseries, zoos, breeder units or aquariums accredited with the CITES administrative authority.

The requirements are as follows under regulation of procedures for import and export permits of wild fauna and flora species for the export of wildlife species included in CITES (Article 1):

- buy and complete the export application form;
- pay the respective sum to the government;
- demonstrate that species destined for export have been reproduced in nurseries, zoos, breeder units or aquariums, through an certificate of origin or an invoice from the authorized establishment; and
- attach authorization or a copy of the import permit of the destination country.

- Those who request an export permit for wildlife species, autochthonous flora and fauna species, shall meet the following requirements (Article 7):
- complete the requisite form;
- pay the respective charge (actually repealed);
- demonstrate that the species to export has been reproduced through a certificate of origin or invoice of the authorized commercial establishment.

These provisions in general are not applied to access to genetic resources, except for species included in CITES, in which case it should be requested. Once the access permit is obtained, the respective CITES certificate for the export of samples is issued. This certificate should be processed at the Unique Window (*Ventanilla Única*) of SINAC.

Legislation on environmental impact assessment in the Law of Environment and the Law of Biodiversity

Chapter VII of Law of Biodiversity deals exclusively with the Evaluation of Environmental Impact of the access projects that the Technical Office considers could affect biodiversity (Article 92). The articles contain provisions on the guidelines for the implementing of impact evaluations, environmental audit and international notification.

The General Law of the Environment (No 7554), establishes that all human activity that alters or destroys environmental elements, or generates residues or toxic or dangerous materials, requires an evaluation of environmental impact by the National Environmental Technical Secretary, created by the same law. Only with its authorization can proposed activities, works or projects be executed (Article 17). It develops policy related to resolutions and their compliance follow-up, diffusion of the information, and access to procedures. The necessary documents explaining the legislation regulate evaluation for projects under CONAGEBIO that could affect biodiversity.

The draft regulations authorize the Technical Office to request a preliminary environmental evaluation (FEAP). This (Article 26 of the draft) will be required when the interested party submits all the necessary information to the Technical Office and before giving the endorsement. Once resolved, the FEAP by the Technical Secretary is supposed to continue with the approval or rejection procedure of the application.

Law of Promotion of Scientific and Technological Development, No. 7169 of 13 June 1990

This law mentions the long-term objectives for scientific and technological development (Article 2), specific objectives (Article 3); and responsibility of the state to meet them (Article 4). Also, it establishes the Ministry of Science and Technology and the National System of Science and Technology. The latter is constituted by all institutions, entities and organs of the public and private sectors, and research and higher education institutions whose main activities are in science and technology. At the same time, it establishes the National Programme of Science and Technology as the instrument of planning for scientific and technological development for the short, medium and long terms (Article 16). It will be part of the National Plan for Development (Article 17), binding on public and private sectors and institutions of higher education. It stipulates the mechanism to register scientific entities dedicated to research, including those relating to biodiversity (Articles 1, 5, 7, 8 and 25 of the Law and 2, 5 and 17 of the Regulation for the Scientific and Technological Register).

Law of Biodiversity for SINAC and Law of Establishment of the National Parks Service

By the Law of Biodiversity, Article 22, the National System of Conservation Areas is decentralized and a participatory system of management and institutional coordination is

established. It develops policies on planning and managing of natural resources, including forests, wildlife and protected areas of the Ministry of the Environment and Energy in Costa Rica. Also, it consolidates the National Council, comprising the Minister of Environment, SINAC Executive Director, Directors of each of the Conservation Areas, Executive Director of the CONAGEBIO Technical Office, and representative of each regional Council of the Conservation Areas, to execute the policies and strategies to manage and develop the Conservation Areas.

Costa Rica has legislation that regulates the protected wild areas, known as “conservation areas”. It has dedicated nearly 25% of its territory to different categories of Protected Wild Areas. The different categories of Protected Wild Areas carry out different property and private activities. The relevant legislation is the Law of Establishment of the National Parks Service, No 6084 of 25 August 1977 (on national parks and reserves), and some related regulations. Under this legislation, the national parks are categories of absolute protection and commercial activities are therefore in general forbidden.

According to Article 8 of the Law of Parks, it is forbidden within the national parks, for visitors to:

- cut down trees and extract plants or any other type of forest products;
- hunt or capture wild animals, gather or extract any of their products or waste;
- hunt marine turtles or any species; gather or extract their eggs or any other product or waste;
- scratch, mark, stain or cause any type of damage or deterioration to plants, equipment or facilities;
- undertake recreational, artisanal or industrial fishery, except as specified in Article 10;
- gather or extract corals, shells, rocks or any other product or waste of the sea;
- gather or extract rocks, minerals, fossils or any other geologic product;
- carry firearms, harpoons or any other instruments that can be used for hunting;
- introduce animals and exotic plants;
- shepherd and water livestock or raise bees;
- cause any type of environmental contamination;
- extract stone, sand, gravel or similar products;
- feed the animals;
- build electric or telephone lines, aqueducts, highways or railroads; and
- carry out any commercial, agricultural or industrial activity.

According to Article 11 of Law, no rights of way can be constituted for particular landed property in national parks. Article 12 prohibits the granting of any concessions for the exploiting of products of the national parks, permits establishing facilities other than services.

Article 10 allows, subject to approval by the Advisory Council of the Service, to authorize recreational and artisanal fishery in certain areas of national parks, when it does not produce ecological alteration. It is deduced that commercial and industrial activities are absolutely forbidden inside the parks, with exceptions that have been allowed in practice to provide some services, such as food, guides, paths and lodging, fundamentally to communities and NGOs. They are strictly limited activities and do not include the management of the areas nor allow the construction of hotels, infrastructure, jetties, etc. Also, due to the incompatibility of private property and the exercise of commercial activities, it should be impossible to purchase or expropriate properties for private ownership. This is because the restrictions to right of property affect its basic core and should be compensated. These prohibitions on the exercise of commercial activities in this management category are

supported in other legal instruments, such as the Convention for the of the Flora and Fauna and Natural Scenic Beauties of the Countries of America, Law No 3763 of 19 October 1976; Article 3 specifies that the existent wealth in the national parks can not be exploited for commercial purposes.

These restrictions are applicable to the national parks and biological reserves¹² and thus, due to the imposed limits, it is required that the state proceeds to the purchase or expropriation of the lands. Article 37 of the Constitutional Law on the Environment, No. 7554 of 4 October 1995, amended by the Forest Law, No. 7575 5 of February 1996, lays down that: in the case of national parks, biological reserves or national refuges of state wildlife, lands will be acquired by purchase or expropriation or both procedures, previous to compensation. Therefore, access to these areas should be considered forbidden (see Article 25 of the draft Regulations on Access).

Fishery Law and Law of Establishment of INCOPECSA

The Law of Establishment of the Costa Rican Institute of Fishing and Aquaculture (INCOPECSA) regulates several aspects of extraction of marine biodiversity.

INCOPECSA should (Article 2):

- coordinate the fishing and aquaculture sector, promote and regulate fishing development, marine hunting, aquaculture and research; and foment, on the basis of technical and scientific approaches, conservation and use of the biological resources of the sea and aquaculture;
- regulate the rational use of fishing resources to achieve greater economic yields, and protect the marine species and aquaculture; and
- elaborate, control and follow-up the application of legislation; regulate and avoid contamination of marine resources and aquaculture, as a result of fishing, aquaculture and activities that contaminate and threaten these resources.
- Also, in conformity with Article 5, the institute will have the following attributions:
- Control the fishing and hunting of marine species in jurisdictional waters, according to Article 6 of the Political Constitution.
- Dictate the measures for conservation, promotion, cultivation and development of marine flora and fauna, and aquaculture.
- Identify species of marine organisms and aquaculture that can be commercially exploited.
- Based on study of existing marine resources, establish the number of licences and their regulation, as well as their technical limitations.
- Grant, suspend or cancel marine fishing and hunting permits, and construction of vessels, as well as the licences and concessions for production in aquaculture, to natural and juridical persons that request them and establish the quantity to be paid for such licences.
- Determine closed seasons and areas, as well establishing minimum size for capture fisheries of the various species.
- Give opinions of technical and scientific character related to marine flora and fauna, and aquaculture.
- Carry out inventories of marine biodiversity and aquaculture in collaboration with the technological scientific sector.

Wo Ching (2002) affirmed that:

¹² Biological reserves are not specifically mentioned at Law of Parks, but Article 14 amends Law of Forest 4465 and states that all concerns on national parks and biological reserves will be up to National Parks Service.

“Similar to the Law of Wildlife Conservation, the Law of Establishment of the INCOPESCA regulates the marine biodiversity, mostly in the level of species, and as relating to contamination, establishing regulations for the level of ecosystems. It does not apply to access to extracted genetic and biochemical resources of marine biodiversity. ... although, the Law of Biodiversity does not distinguish for access permits purposes, between marine or terrestrial biodiversity (or aquatic). Therefore, we have to apply the general principle of law, consisting in not establishing differences where the law does not establish it, and for the same general procedure to request access permits, either marine or terrestrial biodiversity elements. ...

“On the other hand, neither Law of Marine Fishing and Hunting, Decree, Law No. 190 of 28 September 1948 nor its amendments or regulation or Decree, Law No. 363 of 11 January 1949 nor its amendments, contain provisions on genetic and biochemical resources. Like the Law of Establishment of the INCOPESCA, they only regulate the marine fishing and hunting, by the level of marine and coastal biodiversity species. There is no inconsistency between these laws and access provisions of the Law of Biodiversity”.

It is, however, considered that in spite of this, the Technical Office cannot authorize fishing for organic resources that contain a genetic resource. When marine resources are required, INCOPESCA would grant the respective permit, in view of the PIC and subject to obtaining the access permit from the Technical Office.

Law of Seeds

The Law No. 6289 of 4 December 1978 establishes the National Seed Office, attached to the Ministry of Agriculture and Livestock. It promotes and protects, improves, controls the use of superior quality seeds, establishing standards for their circulation and trade (Article 1). The law provides an important explanation about the seeds of use to humans under its regulation (Article 3).

Seed is any grain, tuber, bulb or any living vegetable part used to reproduce a species (Article 5), and a commercial variety is the domesticated botanical single seed distinguished by certain morphological, physiological, cytological, chemical characters or by agricultural or economic characters, that can be reproduced (Article 6).

Equally, we can compare the Law of Biodiversity and Law of Establishment of the National Seed Office (Wo Ching, 2002). The main difference between them is that the authorization of the National Seed Office is given when a well-known use of the seed exists. Its cultivation will be promoted and an access permit is required in case of research on *in situ* or *ex situ* genetic or biochemical elements of a seed in the country.

System of intellectual property

In addition to the Law of Biodiversity No. 7788, are the Law on Patents of Invention, Industrial Drawings and Utility Models No. 6867 of 5 April 1983, amended by Law No. 7979 of 31 January 2000, Law of Marks and Other Distinctive Signs No. 7978 of 1 February 2000, Law of Not Disclosed Information No. 7975 of 18 January 2000, Law on Copyrights and Related Rights, the Law of Intellectual Property Observance No. 8039 of 27 October 2000. Table 2.2 shows the main aspects related to biodiversity.

Table 2.2 A summary of legislation germane to ABS and biodiversity in Costa Rica.

Legislation	Features
Law of Biodiversity No. 7788 27 May 1998	<p>The state recognizes the existence and validity of knowledge and innovation and the necessity of protecting them through appropriate legal mechanisms for each case (Article 77).</p> <p>IPRs are protected by patent, trade secrets, breeders' rights, <i>sui generis</i> community intellectual rights, copyrights, the farmers' rights (Article 78) with the exception of:</p> <ul style="list-style-type: none"> • sequence of DNA; • plants and animals; • not genetically modified microorganisms; • procedures for plants and animals production essentially biological; • processes or natural cycles; • inventions derived from associate knowledge or traditional or cultural biological practices of public property; or • inventions that can affect basic agricultural processes or products for food and health of the inhabitants when being exploited commercially under a monopoly form. <p>It establishes so-called "<i>sui generis</i> community intellectual rights" that recognize and protect the knowledge, practices and innovations of the indigenous peoples and local communities related to the use of biodiversity elements and associated knowledge.</p> <p>This right exists and is recognized legally by the existence of the cultural practice or knowledge related to the genetic and biochemical resources; it does not require previous declaration, recognition or official registration; it therefore comprises the practices that acquire such a category in the future.</p> <p>It establishes certain general approaches in connection with community rights and allows local and indigenous communities to define the form in which they will be protected and registered, applying a participatory process.</p>
Law of Information Not Disclosed, No 7975 18 January 2000, amended 11 January 2001	<p>It protects the commercial and industrial secrets of natural or juridical persons.</p> <p>The "not disclosed information" refers to the nature, characteristics or purposes of products and production methods or processes. It is (Article 2):</p> <ul style="list-style-type: none"> • secret; • legally under the control of a person that has adopted reasonable and proportional measures to maintain it as a secret; • of commercial value; and • protected by the Registration of Industrial Property attached to the National Registration, according to Law No. 5695 (Article 3); but • excludes protection of information that (Article 4): <ul style="list-style-type: none"> • is public property; • is evident for a technician on a previously-available-information basis; • should be disclosed by legal provision or judicial order; and • forbids the use or diffusion without consent of the interested party to all persons who because of work, employment and position have access to not disclosed information, provided that they are aware of it in that express form (Article 7).
*Patents Law No. 6867 5 April 1983, amended 31 January 2000	<p>It patents all creation of the human intellect that can be applied to industry. It can be a product, machine, tool or production process (Article 1)</p> <p>Inventions exclude:</p> <ul style="list-style-type: none"> • discoveries, scientific theories, mathematical methods and computer programs individually; • purely aesthetic creations, literary and artistic works; • plans, principles or economic methods of publicity or business and those referred to purely as mental activities, intellectual or game; • juxtaposition of well-known inventions or mixtures of well-known products, their form variation or use, dimensions or materials, unless it is a combination that cannot work separately or their qualities or functional characteristics are modified to obtain an industrial output not obvious for the technicians; and • plant varieties that will have protection by means of special law. <p>Excluded from protection are:</p> <ul style="list-style-type: none"> • inventions whose commercial exploitation should be impeded to protect public order, morality, health or life of people or animals, to preserve vegetables or to avoid serious damages to the environment; • diagnostic, therapeutic and surgical methods for the treatment of people or animals; and • procedures for plants or animals production that are essentially biological.

*In Costa Rica three applications have been presented before the Intellectual Property Registration for inscription of invention patents specifically related to plant biological procedures. Nevertheless, the three applications were rejected considering that they did not comply with the requirements for the patent. However, it could be determined that these applications are not different from any other application of invention patent (Sánchez Hernández *et al.*, 2002. *Diagnóstico del estado actual de los derechos de propiedad intelectual en Costa Rica, en las áreas de la biotecnología y mejoramiento genético de las plantas*. CRU. Legal Research Institute. Faculty of Law.

Current initiatives regarding ABS: description of the Draft Access Regulations

The draft “General Standards for the Access to the Genetic and Biochemical Elements and Resources of Biodiversity” constitutes the regulations implementing the law governing access. These regulations have already been approved after an internal discussion and consultancy process that lasted about 4 years. At the time of writing, they awaited publication to enter into force.

The Access Regulations are to:

- regulate access to the genetic and biochemical elements and resources of biodiversity, and related knowledge, innovations and traditional practices;
- regulate the fair and equitable sharing of the social, environmental and economic benefits arising from the use of the genetic and biochemical elements and resources of biodiversity to all sectors of society, with special attention to local communities and indigenous peoples;
- protect the *sui generis* intellectual rights of the community;
- facilitate access to the genetic and biochemical elements and resources of biodiversity and promote research and technology as long as these activities do not jeopardize resource sustainability nor run counter to the aims of the CBD; and
- ensure and facilitate access to technologies and their suitable, effective and selective transfer, under favourable and mutually agreed conditions, for capacity building at the national level.

They will be applied to the genetic and biochemical elements and resources of biodiversity components, whether wild or domesticated; land, sea, freshwater or air; and *in situ* or *ex situ* over the national territory, as defined in Article 6 of the Political Constitution, whether private or public property. The access rules will protect and regulate TK, and the fair and equitable sharing of the benefits arising from the use of such elements and resources (Article 2). The rules do not apply to those biodiversity elements used as organic resources, which will be still regulated by the Forest Law, Wildlife Conservation Law, the Law for the Creation of INCOPESCA, the Sea Fishing and Hunting Law, and other special laws (Article 3). In the same fashion, the principles and criteria set forth in Article 9 of the Biodiversity Law should be observed. Definitions other than those contemplated by the Law (Article 6) are presented.

The procedure¹³ established by the Access Regulations is that those interested should register with the Technical Office before applying for any kind of permit (Article 8). Later, the PIC will have to be negotiated, in agreement with a Technical Guide who shall define the basic issues to be discussed (Article 9) between the applicant and the Conservation Area, the Indigenous Peoples Territory, the owner of the land or the biological resources (including not only individuals, but also other government bodies, such as municipalities and the Institute for Agrarian Development) and *ex situ* collections.

After having obtained the PIC (which will supposedly contain the MAT that ensures the fair and equitable sharing of benefits), the agreement must be endorsed (i.e. approved) by the Technical Office, who simply endorses the document (i.e. no further negotiation is required with this office). The approval document establishes the following: the obligation to materially perform the activities authorized by the corresponding resolution, permit deadline, interested party's obligation to deposit up to 10% of the budget for the investigation and up to 50% of the royalties in favour of the resource provider, and frequency of the reports to be presented (Article 13).

¹³ Not discussed here, but the requirements or the data called for are indicated in the later charts.

According to the Access Regulations, the interested party must fill in an application form and a Technical Guide (Article 9) and present them at the Technical Office. The rules also establish the requirements and the accompanying documents to be presented, and the additional requirements for those who apply for permission for basic research, bioprospecting and access for economic use, whether occasional or repeated (Article 9). This includes the application form, the technical guide and the PIC

Article 13 provides that the resolution issued by the Technical Office must clearly indicate whether the application was accepted or rejected, and must bear the technical, social and environmental rationale behind the resolution. Once the access permit has been approved, the Technical Office shall issue an "Access passport" that authorizes the admission of the interested party into the site where the authorized activities will materially take place. A written record of the authorized activities shall be kept.

The approval resolution will establish, *inter alia*, the following conditions:

- Permit deadline.
- The interested party's obligation to deposit up to 10% of the research budget and up to 50% of the profits in favour of the resource provider, if applicable.
- The interested party's obligation to report on the activity and related reporting frequency.
- Any other condition or restriction the Technical Office will deem necessary.

Upon evaluating or approving the permit application, the Technical Office will also bear in mind (Article 14) the criteria of the public interest principle and precaution principle stated in international agreements, regional protocols and national laws, so as to ensure the:

- development options for future generations;
- food safety and sovereignty;
- conservation of ecosystems;
- protection of human health;
- improvement of citizens' quality of life;
- gender equity; and
- adherence to the objectives of conservation, sustainable use and fair and equitable sharing of benefits derived from the access to genetic and biochemical elements or resources and related TK.

A summary of the applications and eventual resolutions shall be published on CONAGEBIO's Web page within 8 days of issue, observing confidentiality and keeping commercial and industrial secrets that the interested party indicated in the data furnished along with the permit application and accompanying documentation, and in conformity with the Non-Disclosure Information Law No. 7975 (Article 15). The office shall also write an annual report on the access permits granted through the country and shall send it to the Clearing House Mechanism of the CBD. The interested party may challenge the resolution with the Technical Office, or lodge an appeal with CONAGEBIO (Article 16 of the Access Regulations Draft).

Both the law (Article 76) and the Access Standards (Article 17 about administrative taxes) require that the amount that the interested party must pay for processing expenses be fixed. The Technical Office shall issue a certificate of origin (Article 19 of the Rules), and publish the applications and related final resolutions.

After access has been authorized, the Technical Office shall start the verification and control phase (Article 20 of the Access Regulations) in coordination with the authorized representatives of the site where the access to resources will materially take place. This will

comply with the agreements and commitments established for each and every phase of the standards.

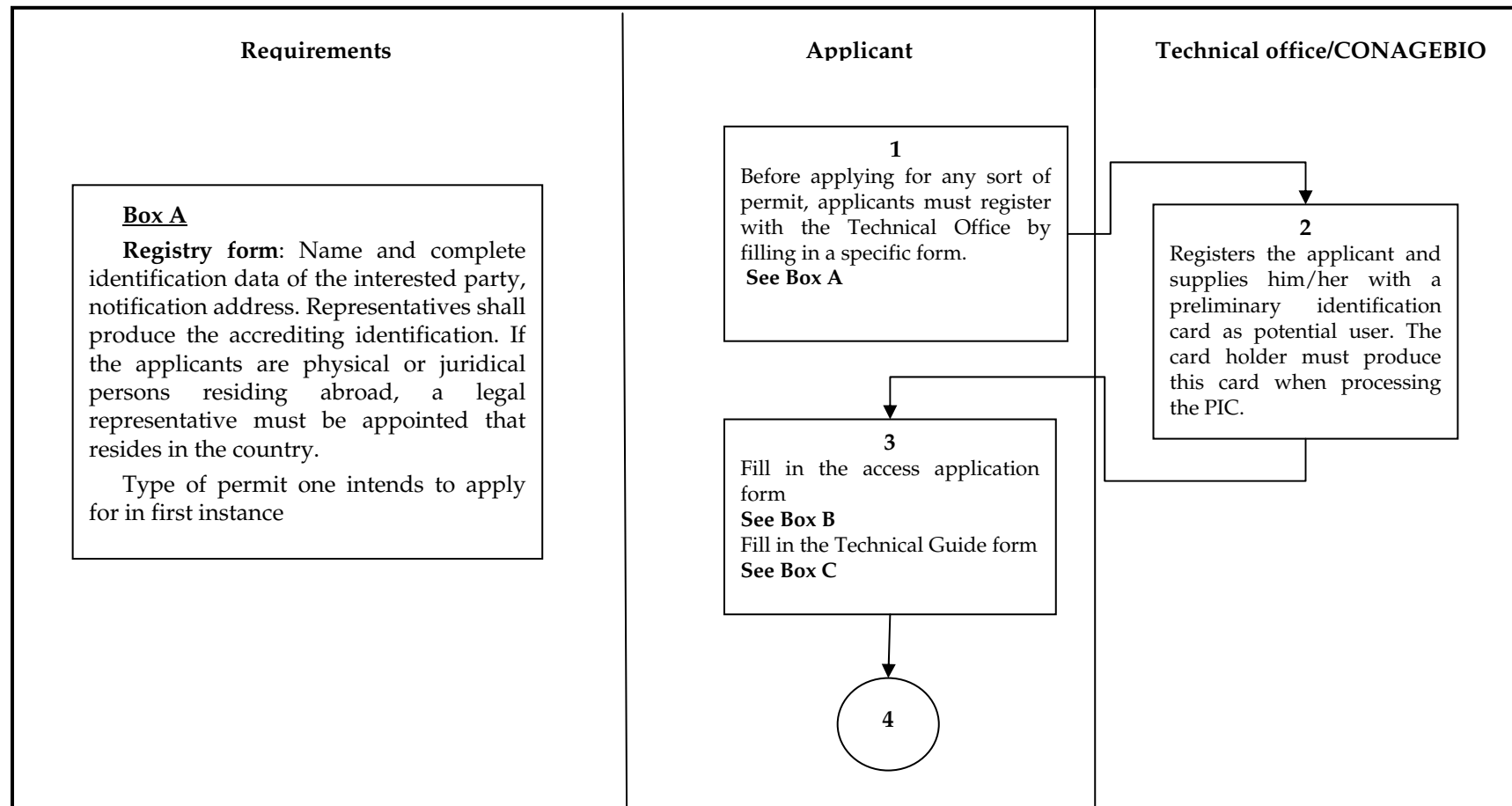
Sanitary and phytosanitary requirements must be observed wherever applicable (mainly the Phytosanitary Protection Law and several other decrees) for the exportation of the materials.

Framework agreements are regulated (Article 21) with public universities. Other duly registered research centres or institutions will be able to periodically sign (as the Technical Office sees fit), framework conventions with CONAGEBIO to process permits for the access to genetic or biochemical elements or resources of biodiversity for basic research, bioprospecting and commercial use. Related reports on the operations shall be handed in. The legal representatives of those universities or institutions that invoke this right shall be civilly and penally responsible for the use they will make of such elements and resources. CONAGEBIO Technical Office (Article 22) shall authorize agreements and contracts signed between national or foreign individuals, or between them and the institutions registered for the purpose, contemplating access to genetic and biochemical elements or resources. In order to have these conventions and contracts processed and approved, the interested parties shall observe what the present standards and Articles 63, 64, 65, 69, 70 and 71 of the Biodiversity Law provide, regarding basic research, bioprospecting and economic use. Upon revision and approval, the provisions of the Non-Disclosure Information Law No. 7975, shall be observed. Whenever the convention or contract is signed after the access permit has been granted, the permit holder shall present it at the Technical Office for due authorization. Otherwise the permit shall be cancelled.

The regulations also establish permit granting restrictions (Article 24), criteria for an environmental impact assessment request (Article 26), factors that entail permit cancellation (Article 27) and sanctions against unauthorized access (Article 28). No access permit shall be granted to *ex situ* collections until specific regulation mechanisms are generated in accordance with the provisions of Article 68 of the law, six months after the access regulations have been published (Transitory 1). A similar moratorium is foreseen for access to related knowledge until a procedure is established to fix *sui generis* community rights.

Chart of the procedure to access genetic resources

Figure 2.1. Rules for the access to genetic and biochemical elements and resources associated with Biodiversity. In all cases Biodiversity Law No. 7788 is applicable and the competent body is CONAGEBIO's Technical Office



Box B

Application form (Art. 9, Subsection A):

(A: Name and complete identification data of the interested party, including the notification address. If a representative, data of the responsible person and accreditation papers; (B) If the applicants are physical or juridical persons residing abroad, a legal representative residing in the country shall be appointed. Duly registered national research institution may act as legal representatives; (C) Type of permit: basic research, bioprospection or economic utilization; (D) Project title.

The following should also be included:

- a. Legal status certification, when applicable.
- b. Photocopy of the identity card, passport or juridical card of the interested party and the researcher responsible for the project.
- c. Documents accrediting representation, when applicable.
- d) If necessary, the contract in conformity with art. 22 of this norm.

Applicant

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The applicant must also produce the following documents:

- a. Previous informed consent and mutually agreed conditions

See Box D

- b. The form specific to the type of permit one intends to apply for at the technical office (Technical Office):

- Research and bioprospecting (Art. 69 Biodiversity Law)

See Box E

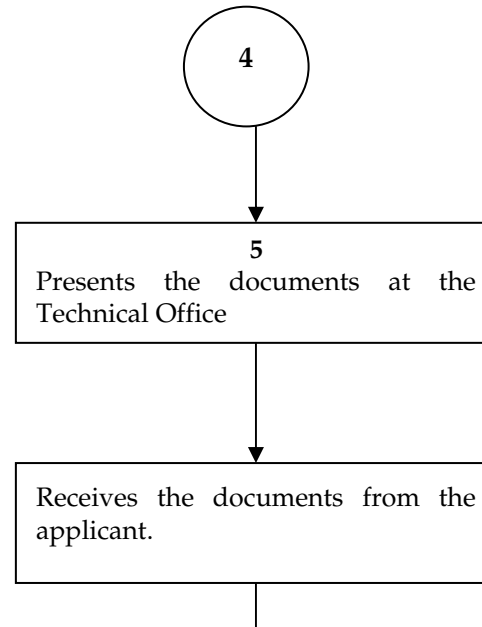
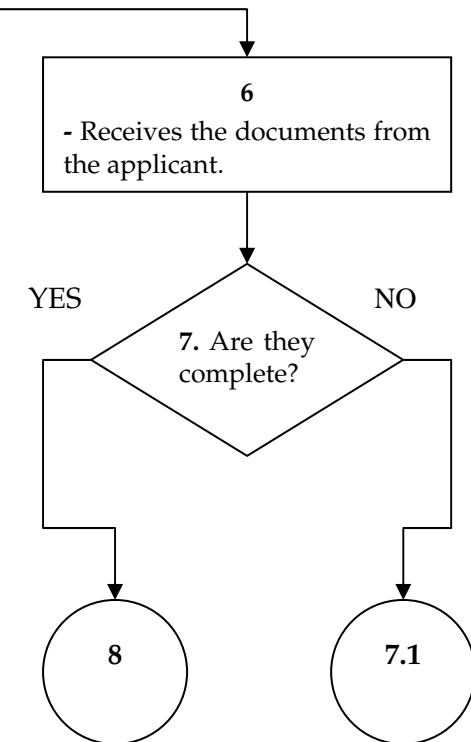
- Economic utilization occasional or constant (licences: Art. 75 Biodiversity Law)

See Box F

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Box C**Technical guide (Art. 9, Subsection B):**

(a) Name and complete identification data of the interested party or their representative; (b) Name and complete identification of the research or bioprospecting leader of the project or of the economic utilization permit holder; (c) Aims, purpose and description of the scope of the project; (d) Geographic location of the site where the access will take place, indicating the owner of the property and the owner or the person responsible for materials kept *ex situ*, including geographic coordinates, and declaration of the type of area, namely protected forest area, indigenous territory, marine or fresh-water area; (e) Approximate access duration and number of times one intends to enter the site; (f) Type of material one is interested in and approximate quantity of material needed; (g) Methods used for the collection of material; (h) Name and complete identification data of the national or international counterpart in the activity, if applicable; (i) Potential destination of the resources and subsequent destinations; (j) Use that will be made of the local traditional or indigenous knowledge associated to the use of biodiversity resources, if applicable; (k) Studies and research work that attest to the knowledge about the elements or resources one requests access to; (l) Description of the way in which the activity will contribute towards the conservation of species and ecosystems; (m) Potential risks of environmental and cultural impact; (n) Chronogram; (o) Statement that everything that has been declared is tantamount to a declaration under oath.

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Box D

Prior Informed consent and mutually agreed terms (Art 9, Subsection C), the contractual guide includes:

9a) Aims of the project; (b) Place where the search or utilization will take place; (c) Number of persons admitted to the site and how to identify them. If guidance or accompaniment by persons from the local communities or indigenous peoples is required, this service must be contracted and paid for, if both parties agree to it; (d) Type and quantity of material required; (e) Methods used for the collection or use of material; (f) Starting price per sample extracted, when applicable; (g) Approximate duration of the process and the number of times the site will be accessed; (h) Potential fate of the extracted elements and their subsequent fates; (i) The interested party's formal commitment to always mention the origin of the resource and related knowledge in any publication, procedure or later use; (j) Agreed terms (ATs) about the exchange of knowledge regarding the characteristics, qualities, uses, procedures, and care of genetic and biochemical elements and

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7.1

If the documentation is incomplete, the Technical Office grants the interested party a maximum period of 10 working days to present the papers missing in the application.

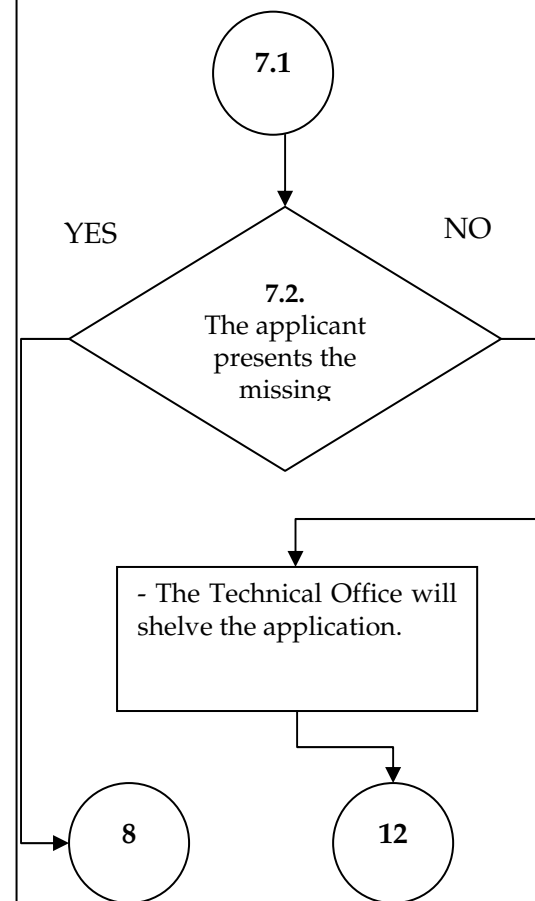
7.2

Box D. II

(Art. 9, Subsection C):. (k) ATs about any other kind of information that the practice or the participatory process with local communities and indigenous peoples has shown as necessary; (l) Acceptance by the interested party of the measures to protect related knowledge, practices and innovations in compliance with *sui generis* Community Intellectual Rights; (m) **ATs** about the assessment of the potential cultural impact, if applicable; (n) ATs about the type and form of technology transfer or generation of information derived from the research, bio-prospecting or economic utilization, towards the national counterparts, local communities, indigenous peoples and resource provider; (o) ATs about the equitable sharing of environmental, economic, social, scientific or spiritual benefits, including potential commercial gains, in the short, medium and long term, of some product or subproduct derived from the acquired material. The TO will see to it that these terms will be complied with in accordance with CBD's third objective; (p) Approximate estimation or the period within which benefit-sharing should be effected; (q) Special emphasis should be made so that both men and women will, as far as possible, equitably participate in the granting of the prior informed consent;
(Continues in the next page....)

Applicant

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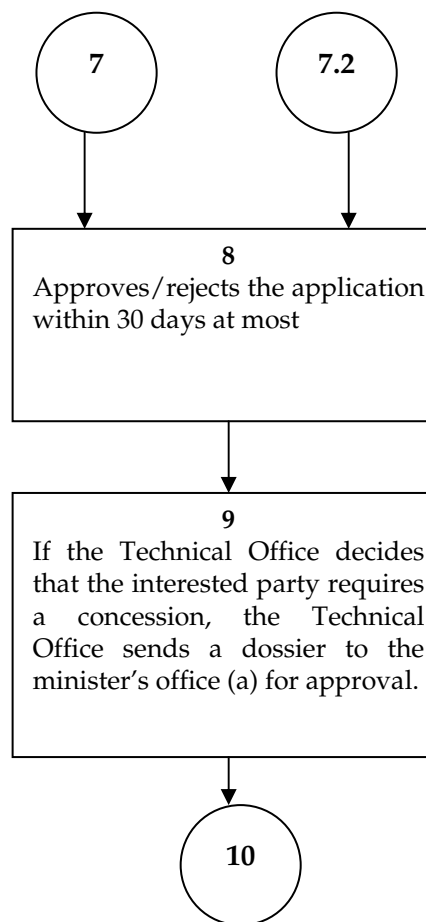
Box D, III

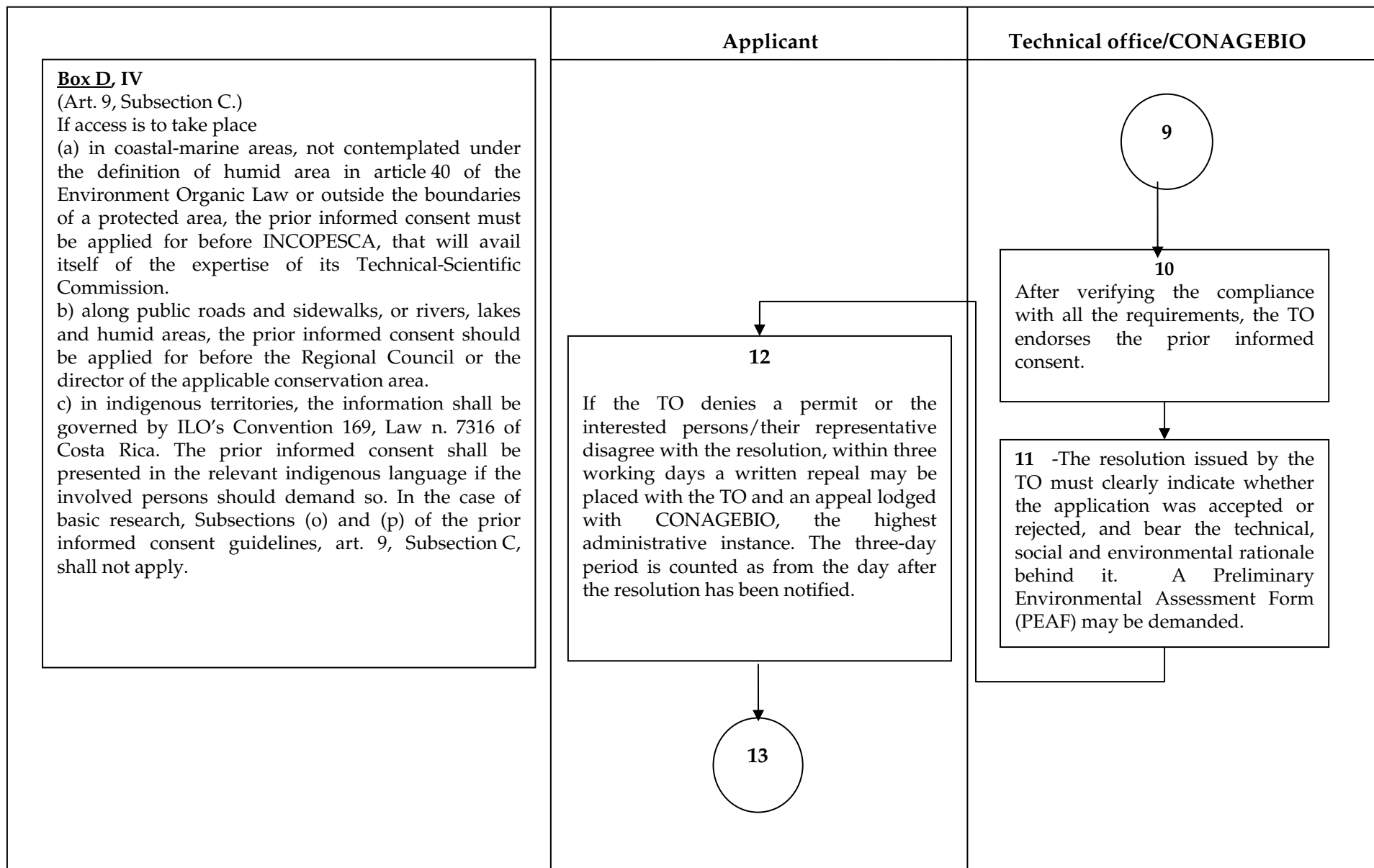
(Art. 9, Subsection C):

r) The provider's and applicant's signatures or fingerprints shall formalize the agreement over the access terms; (s) In the case of research or bioprospecting, the resource provider, the National System of Conservation Areas, the authorities of the local communities/indigenous peoples, land owners, or the owners or persons responsible for materials kept *ex situ* and the interested party will settle on an amount of cash up to 10% of the research or bioprospecting budget; t) Other ATs. Depending on the place where the access will take place, the interested party or their legal representative must address the Director of the Regional Councils of the Conservations Areas, the authorities of the local communities/indigenous peoples, land owners, or the owners or persons responsible for materials kept *ex situ* to discuss in depth the meaning and scope of the access, the requested terms for the protection of the related knowledge, and the practical, logistic and economic aspects of access.

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Box E

Basic research and bioprospecting (Art 9, Subsection D)

In addition to the requirements laid out in points A, B and C, the interested party shall: (a) present a sworn statement, in the format established by the TO, that in case the purpose of the permit for bioprospecting or economic utilization were changed in any way, the interested party will comply with the established requirements. (b) hand in at least three copies of the final outcomes of the basic research and/or the bioprospecting and of the scientific articles and publications deriving from them, in which acknowledgement shall be made of the contribution by the country and the knowledge associated to the relevant resource(s). The copies will be given to the TO, the relevant conservation area, and the owner of land or provider (one copy each). If the research were conducted in a language other than Spanish, at least one executive summary in Spanish shall be added. (c) deposit at least 10% of the research or bioprospecting budget. The percentage shall be agreed upon by both parties. In the resolution granting the access permit, the TO shall establish the contracted obligation and shall give the researcher/bioprospector 8 working days as from resolution notification to make the deposit. The said percentage will depend on the number and the price of the requested samples.

Applicant

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- Must pay the amount due for processing, administrative taxes and other expenses into CONAGEBIO bank account.

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-The granting of a permit does not waive the obligation to comply with the duties stipulated by the national legislation as regards the exportation of plants, animals, seeds, or parts of the same obtained from the access Phytosanitary Protection Law. And CITES.

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Once the access permit has been approved, the technical office shall issue an "access passport" that authorizes the admission of the interested party into the site where the authorized activities will materialize.

See Box G

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TO shall give the applicant a certificate of origin, also called "certificate of legal provenance", which features place and date of access, owner of the biodiversity elements/resources, nature and quantity of the material obtained, the person/community(ies) that have contributed/will contribute with their knowledge. It will also state whether the interested person has complied with the rules.

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Box F

Economic utilization, occasional or constant (Art. 9, Subsection E)

In addition to the requirements laid out in points A, B and C, the interested party shall comply with the following:: (a) Description of the intended commercial use of the genetic and biochemical elements/resources of biodiversity to be extracted. (b) General information about the economic feasibility of the project. (c) Obligation to pay up to 50% of the royalties in favour of: SINAC, local communities/indigenous peoples, land owners, owners of, or people responsible for, materials kept *ex situ*, where the economic utilization will take place, according to the terms established or defined in the contract contemplating the prior informed consent with the approval of the TO. (d) If the interested party is the owner of the good that contains the genetic or biochemical resources, s/he shall pay CONAGEBIO up to 50% of the obtained royalties. Such obligation will be fixed by the TO in the permit approval resolution, indicating the bank account in case the deposit is due. (e) In the case of constant use according to art. 6, Subsection h, after OT's authorization, the process for obtaining a concession will be required as provided for in article 11. No concessions shall be granted for access to national parks of biological reserves.

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- Publishes a summary of the applications
- Publishes final resolutions in CONAGEBIO's Web page (within eight solar days after their issue).
- Observes confidentiality and keeps commercial and industrial secrets as the interested party shall indicate as such (Non-disclosure of Information Law No. 7975).

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	Further Technical Office provisions	Technical office/CONAGEBIO
<p>Box G</p> <p>Approval resolution. Criteria. (art. 13)</p> <p>The approval resolution will establish, <i>inter alia</i>, the following conditions:</p> <p>(a) Permit deadline; b) the interested party's obligation to deposit up to 10% of the research budget and up to 50% of the royalties in favour of the resource provider, if applicable; (c) the interested party's obligation to report on the activity and related reporting frequency; and (d) any other condition or restriction the technical office will deem necessary. The reasons for imposing total or partial restrictions as laid out in article 24 must be considered.</p> <p>Additional criteria (art. 14)</p> <p>Other criteria the OT must bear in mind upon evaluating applications are the: (a) development options for future generations; (b) food safety and sovereignty; (c) conservation of ecosystems; (d) protection of human health; (e) improvement of citizens' quality of life; (f) gender equity; and (g) objectives of conservation, sustainable use and fair and equitable sharing of benefits derived from the access to genetic and biochemical elements or resources and related TK.</p>	<div data-bbox="992 432 1469 699"> <p>Knowledge of local/indigenous communities</p> <p>The TO may grant none of the three permits when the knowledge and practices of local/indigenous communities are involved and the procedures relevant to the prior informed consent have not been complied with.</p> </div> <div data-bbox="992 794 1469 1110"> <p>Ex situ</p> <p>CONAGEBIO shall establish the procedure for access to biochemical and genetic resources <i>ex situ</i> six month after the publication of the rules for access to Genetic and biochemical resources of biodiversity.</p> </div>	<div data-bbox="1541 312 2020 1347"> <pre> graph TD 17((17)) --> 18[18] 18 --> 19[19] </pre> <p>17</p> <p>18</p> <p>- Writes an annual report on the access permits granted through the country and sends it to the Clearing House Mechanism of the Convention on Biological Diversity.</p> <p>19</p> <ul style="list-style-type: none"> • Carries out verification and control tasks in coordination with the authorized representatives of the site where the access to resources will take place. • TO officers will make official reports. • La OT shall hear claims and investigate presumed violation of terms. Non-compliance with the agreements will entail permit cancellation. </div>

Figure 2.2. Framework agreements, contracts and agreements among individuals

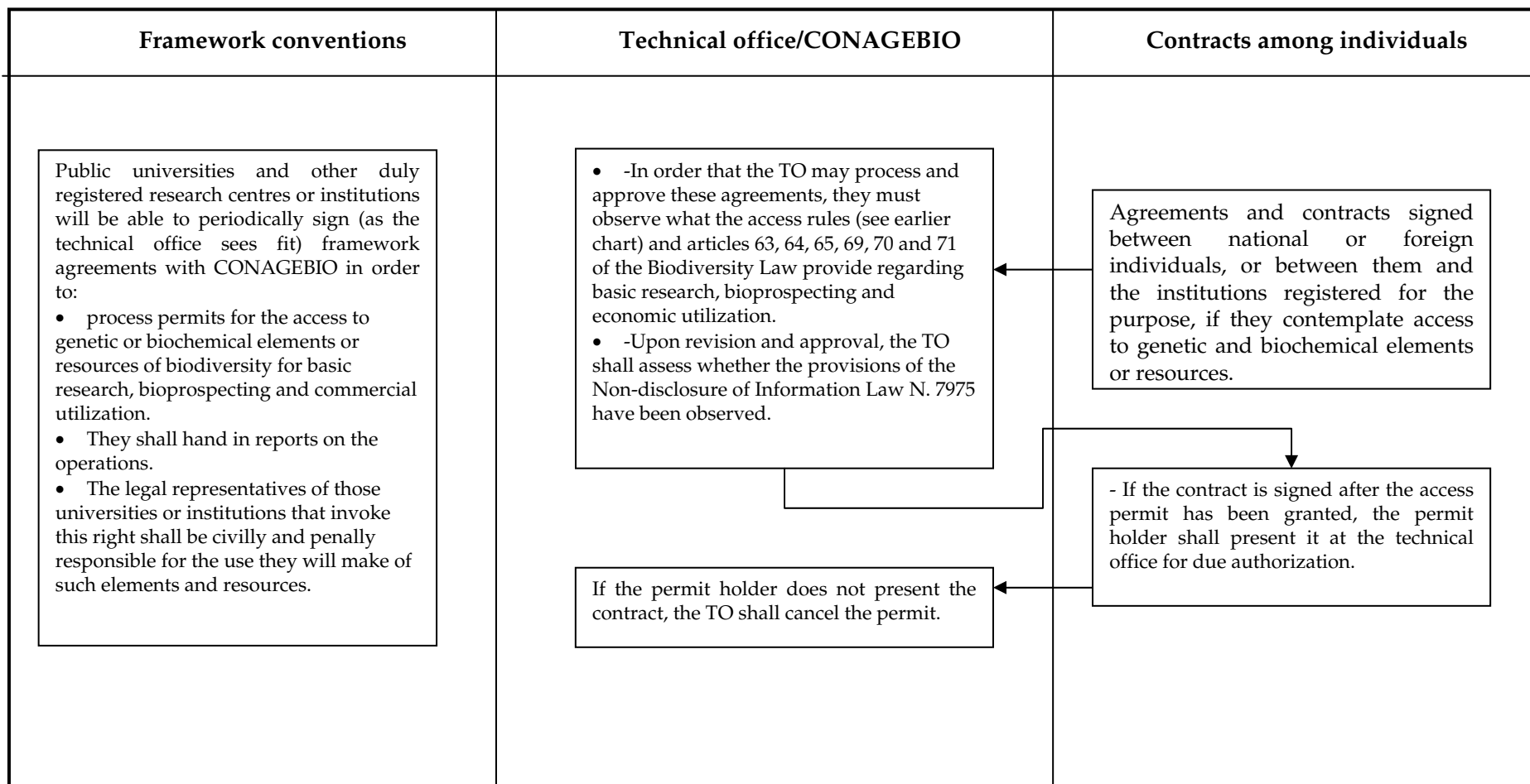
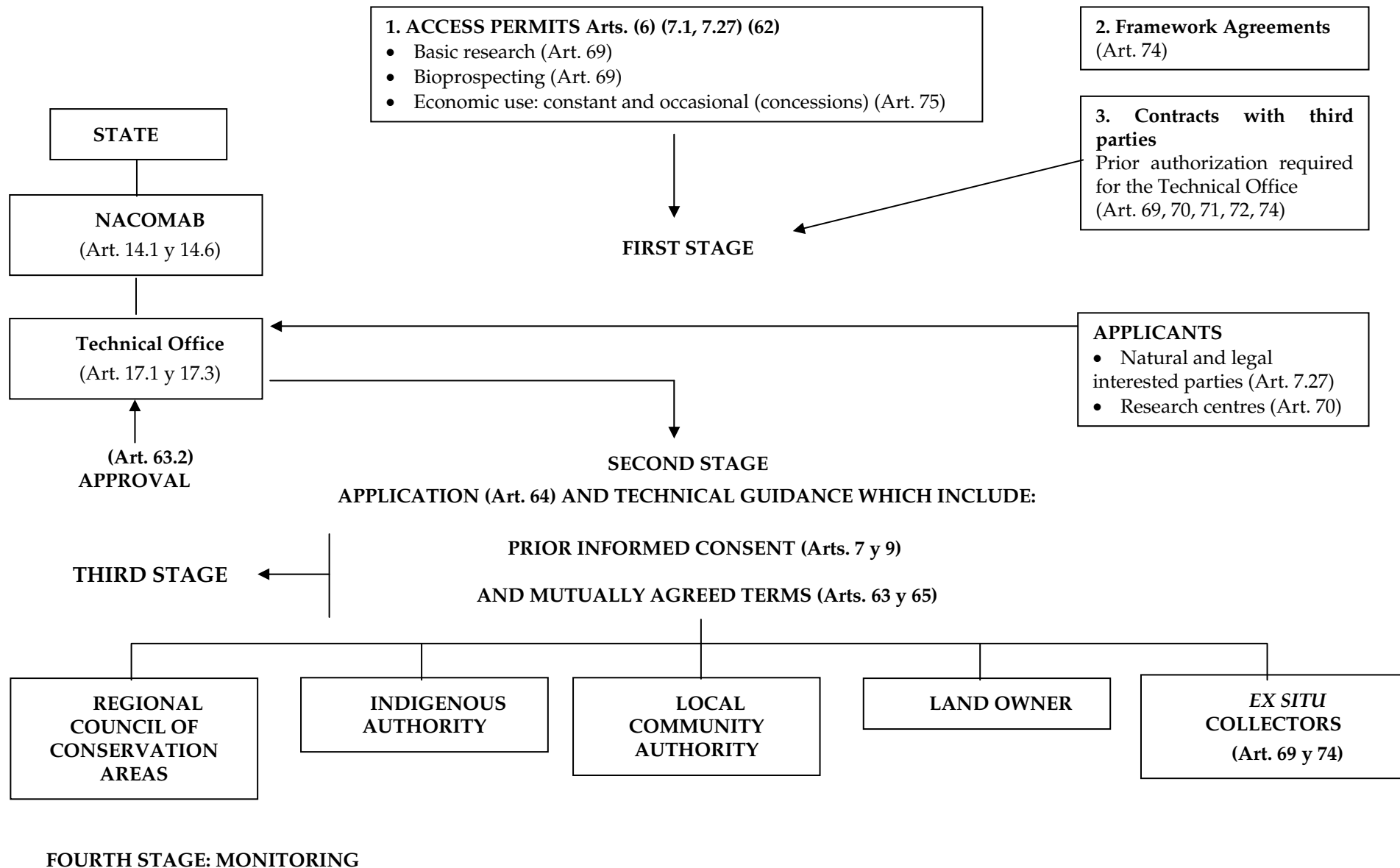


Figure 2.3. Access procedure to biochemical and genetic resources flow chart



Access applications prior to the Biodiversity Law

Access applications

The records of applications which were started before the CBD and the law, but continued after the Biodiversity Law was in force, regard those by INBio. However, there may be other applications involving access by public or private institutions, presented and processed as research permits, of which SINAC has no records or information. Those that involve INBio areas are as follows:

- The state has not participated directly, but has granted the collection permits to INBio, which participated in the negotiations for access with other enterprises.
- INBio has an agreement with MINAE to carry out specific activities regarding the national inventory and use of biodiversity in government-protected areas. According to this agreement, INBio gives MINAE 10% of the operative research budgets in collaboration agreements signed with enterprises, 50% of any future royalties or milestone payments, as well as training and education for SINAC officers.
- Research is done in collaboration with research centres, universities and national and international private enterprises, through research agreements. They include access (to a limited extent and for a limited period only), equity and compensation (research budget, technology transfer, training and sharing of benefits).

INBio access policies entail the following (Tamayo *et al.* 2003):

- They facilitate access to a limited quantity of natural resource samples for a limited period of time (terms are exclusivity limited).
- A significant part of the research should be conducted locally, and the related expenses shall be totally covered by the industrial partner (defined as research budget).
- Payments intended for conservation (minimum 10% of the research budget is transferred to MINAE for conservation purposes).

Benefit-sharing mechanisms must be previously negotiated and must include:

- milestone payments for the discovery and development of the phases of a potential product, which must be shared at 50% with MINAE;
- a percentage of the profits from the net sales of the final product (including derivatives from the original products and from the technology), which must be shared at 50% with MINAE;
- the participation of Costa Rican scientists must be included wherever applicable;
- technology transfer and the training and education of local scientists must be proportional and must include state-of-the-art technology; and
- the discovery and development of a product should not affect biodiversity, but should be consistent with the national legislation concerning the access to genetic resources.

Access procedure

The procedure was as follows:

- In all cases, the permit application was presented at SINAC's Unique and was approved after completing a printed form with basic information.
- All cases regarded collections in Protected Areas that are property of the state.
- The profits were to be shared as contemplated by the INBio-MINAE convention.
- The objectives are stated in each of the different agreements.

- The mean time for approval was 2 weeks as from the creation of the Unique Window. Prior to that, one had to apply for a permit to access each of the protected areas where one wanted to take samples. This slowed down the process substantially, although the response times varied according to the protected area in question.

Below is a list of collaboration agreements on the grounds of a research permit granted in conformity with the Wildlife Conservation Law.

Research agreements in collaboration with industry

INBio-Merck. Research into sustainable uses of biodiversity in Costa Rica. This was the first agreement signed with a commercial company (October 1991) to find biodiversity in Costa Rica with potential for the pharmaceutical and veterinary industries. It was renewed in 1994, 1996 and 1998 under similar terms. The agreement included the study of a limited number of plants, insects and environmental samples in order to determine their potential use. The agreement allowed INBio access to technology, personnel and training.

Chemical prospecting in a Costa Rican conservation area. The project started in 1993 and ended in September 1999. This was one of the five international cooperation groups working on biodiversity in the world, financed by USA National Health Institutes. It took place in Guanacaste Conservation Area in collaboration with the University of Costa Rica, University of Cornell and Bristol Myers Squibb. The aim was to search in tropical insects for new drugs, and increase human resource capacity in ecology, taxonomy and ecochemistry.

INBio-Givaudan Roure Agreement (Fragrances and Aromas). As a result of the continuous search for new options, in 1995 INBio started a phase of exploration for potential fragrances and aromas of our biodiversity. The aim was to determine the feasibility of new products from volatile compounds of Costa Rican biodiversity and the transfer of technology in this field. The activities in Costa Rica envisaged by the agreement finished by mid-1998.

INBio-BTG-Ecos La Pacifica Agreement (The agricultural area). INBio was trying to integrate the outcomes of bioprospection work with the economic development of Costa Rica. The signing of an agreement between INBio and the British Technological Group (BTG) in 1992 enabled INBio to continue research on characterizing and producing a nematode control product (DMDP) from a tree in the dry tropical forest. At the same time, research was carried out with Ecos La Pacífica Corporation, with the aim of determining species growth conditions and DMDP production, as well as the effectiveness of the nematocide on tropical plants.

INBio-Diversa Agreement: Search for extremophilic enzymes with an application in the chemical industry. In 1995, INBio signed a research agreement with the biotechnological industry DIVERSA, which was renewed in 1998, to explore new enzymes in aquatic and terrestrial microorganisms of the Costa Rican biodiversity. The agreement entailed the collection of bacteria in different conservation areas in Costa Rica to identify and isolate new enzymes of use in the industry. It was also for the training of Costa Rican scientists in collecting and isolating from microorganisms, and cloning and characterizing enzyme genes using molecular biology methods.

INBio-INDENA SPA Agreement (Search for antimicrobial and antiviral components). In 1996, INBio and the phytopharmaceutical company INDENA, based in Milan, Italy, signed an agreement, whose second phase started in 2000. The aim was to obtain antimicrobial compounds for use as active ingredients in cosmetics. Selected extracts from plants were tested and evaluated to determine their antimicrobial activity. The final process took place in INDENA.

INBio-Phytera Inc. Agreement. Traditionally, medicines were developed from extracts from leaves, roots and other parts of the plants. With advances in biotechnology, it is now possible to derive cell cultures from extremely small samples, and induce the production of a wide variety of chemical substances in higher concentrations than those obtained from the original plant. The agreement lasted from 1998 to 2000.

INBio-Eli Lilly Agreement (Search for new compounds). This project started in 1999 and ended in 2000, in collaboration with the pharmaceutical company Eli Lilly & Co to search for botanical compounds with a pharmaceutical application.

INBio-Akkadix Corporation Agreement (Search for nematode control compounds). This project was carried out by the Akkadix Corporation from 1999 to 2001. Its main aim was the search of alternatives for nematode control.

Agreements with the academic sector

INBio-University of Strathclyde Agreement. This agreement led to access to new technologies and methods, and interaction, through the University of Strathclyde and the Japanese private sector. INBio furnished a limited number of plant extracts to be evaluated by several Japanese industries for a limited period of time. The agreement was from 1997 to 2000.

INBio-University of Massachusetts Agreement. The collaborative research with the University of Massachusetts, USA, with support from the National Health Institutes, focused on compounds with insecticide activity.

INBio-University of Guelph (Development of new technologies for plant-based medicines). This agreement covered 2000–2003. The research was aimed at identifying and selecting medicinal plant species from international collections, and developing novel technologies for optimizing, characterizing and mass-producing plant-based medicines.

Other agreements

Validation of threatened plants. This project was financed by the CR Foundation, USA. It had three subprojects to obtain information and to improve the quality of life of Costa Ricans. In collaboration with CIDPA, two plants were studied to isolate active components against malaria. This research gave continuity to the best results from the International Cooperative Biodiversity Group (ICBG) Project. In collaboration with Electronic Microscopy Unit (UME), Biological Tests Laboratory (LEBI) and the National Children's Hospital, these plants were used in the treatment of gastritis in view of their anti-*Helicobacter pylori* activity. Some species were validated for their alkaloid content in order to explore their economic feasibility.

The Chagas project. INBio, together with EARTH, the National University of Costa Rica and other Latin American institutions in Argentina, Brazil, Chile, Mexico and Uruguay, and LEBI NASA in the USA, are part of the project *Espacio Chagas*, a research proposal to help find a solution to one of the most critical health problems in Latin America, Chagas' disease, caused by *Trypanosoma americana*. In 1997, INBio conducted research on plants exerting an inhibitory action on the disease. In 2001, the USA Congress approved a fund to refinance the project, after which biological tests have been resumed.

INBio-IDB Agreement (Support to the use of biodiversity by small enterprises programme). In February 1999, INBio signed an agreement with the Inter-American

Development Bank (IDB) to formalize the terms of a non-refundable technical cooperation, with the aim of promoting the sustainable use of biodiversity by small enterprises.

Cooperative agreements, contracts and regional agreements affecting ABS include:

- **Central American Protocol of Access to Genetic and Biochemical Resources and to Related TK.** Currently in the approval process. Its aim is to regulate access to biochemical and genetic resources, and to the related knowledge, innovations and practices in any of the member states of the Central American Commission of Environment and Development (CCAD).
- **Convention for the Conservation of Biodiversity in Central America.** This convention establishes that CCAD member states commit themselves to protecting biological, terrestrial, coastal and marine biodiversity of Central America for the benefit of present and future generations. Article 7 states the necessity of recognizing and preserving the knowledge, practices and technological innovations developed by the natives in the region, which may contribute to the use and conservation of biological resources. Article 8 establishes that access to genetic material, substances, derived products, and related technology and their conservation will be available under the jurisdiction and control of the states within mutual agreements with recognized bodies.
- **INBio-MINAE Agreement.** It does not replace research permits, but collaborates with, and supports, the access-related work done by the institute, and sets general criteria for benefit-sharing.

There are several regional agricultural cooperation networks that involve the access and transfer of materials for research purposes. The cooperation networks involving beans (Profijol), maize (Maize Regional Programme) and coffee (Promecafé) entail the participation of national research bodies, with the help of international cooperation; they also exchange materials and research results.

Access applications after the enforcement of the Biodiversity Law

The law was enforced in 1998, but has not been implemented in practice owing to its possible unconstitutionality, especially the claims regarding CONAGEBIO jurisdiction. Several applications have been presented informally, but none have been processed or accepted or rejected. The applications informally presented are:

- Application by the University of Madison-Wisconsin to collect wild potatoes in some areas of the La Amistad National Park. They declined and cancelled their application with Costa Rica, because they were denied permission by Panama to collect wild samples.
- Application for access to cyanobacteria by an institute from Florence, Italy. The application did not prosper because the institute in question only presented a preliminary document, but did not continue with the process.
- Application by the National University to access wild material of the genus *Sechium* (chayote and tacacos) in some protected areas and in an *ex situ* collection. SINAC's Sole Window granted the permit, but as a plain research permit.

New applications are informally present at CONAGEBIO, which is waiting for the publication of the access regulations in order to be able to process the applications. Applications involving bioprospecting by INBio are processed according to the cooperation agreement between INBio and MINAE through the Unique Window, in conformity with the Wildlife Conservation Law.

Difficulties of varying nature, legal and other, in the functioning of access regulation mechanisms

Prominent difficulties in the practical application of the law include:

- conceptualizing of accessing and using genetic and biochemical resources, as opposed to using organic or natural resources that do not involve access and are therefore not regulated by the applicable legislation. Access to medicinal plants, nutraceuticals and taxonomic research is cause for concern in various sectors. Likewise, some requirements for the granting of a percentage of basic research budgets may constitute a major obstacle for students or centres with scarce resources. The definition of occasional *vs.* constant access, scope of the exceptions granted to public universities, and what 'non-profit' implies are all conceptual barriers to the adequate functioning of the access system;
- conflicting interests on access and opinions, often contradictory, about how and what should be regulated. Researchers and users are demanding clear, simple and transparent rules that promote and encourage research into biodiversity, whereas social groups are trying to restrict and control prospecting activities and the use of genetic resources for commercial purposes. To reconcile different interests is not always easy, given divergent views: some regard bioprospecting as a synonym for biopiracy and others as the immediate solution to the challenge posed by the conservation of biodiversity;
- wide participatory process that led to the writing of the Law of Biodiversity which affected, to some extent, its technical aspects, especially as regards some complex juridical matters associated with administrative law and the jurisdiction of public authorities. After reflection on the contents of the law, voids and contradictions have become evident, many of which require changes in the legislation, that must be approved by the Legislative Assembly;
- critical aspects that call for a more meticulous study, such as access to the collections *ex situ*; links between access and conservation of biodiversity; role of the state (through CONAGEBIO) in the negotiation and approval of access applications, sample exportation, how to establish efficient monitoring and control mechanisms; and content and the implications of framework agreements. The reasonable, proportioned regulation of *ex situ* collections is a critical challenge in terms of laying down policies and regulations, considering resources acquired under permits obtained in conformity with the other legal frameworks;
- institutional know-how and experience in key matters regarding the negotiation of agreements and contracts, determining what exactly is "fair and equitable", identifying markets and existing parameters so as to be able to distribute benefits among the various sectors (pharmaceutical, agricultural and personal care). A major priority is to organize highly skilled, interdisciplinary teams;
- uncertainty about prospecting; the myth of bioprospecting (the green gold mine) and the expected returns. The word "prospecting" comes from, and has long been used in the exploration of minerals and hydrocarbons. At the beginning of the 1990s, Thomas Eisner was credited with the coining and popularizing of the term 'bioprospecting'. The two types of prospecting entail different levels of risk, and hence benefit-sharing will be determined by the nature of the activities carried out. Several studies have discussed the potential benefits, but bioprospectors never know exactly what they will find in the rich tropical forests. Biodiversity richness does not necessarily translate into marketable products, such as new drugs or seeds. Those who had the illusion that prospecting would become a green gold mine have now changed their position. Bioprospecting is a wider strategy for conserving and using biodiversity, rather than the solution to the immediate need for conservation;
- role of the state and procedures, whether absolute control or regulation and support. Historical inequities have probably led to perceiving the need for strict control to avoid so-

called biopiracy. The regulation mechanisms in some countries, e.g. the Philippines, have shown that in spite of the proponents' good intentions, this kind of approach results in disregard of CBD objectives and national laws. In this sense, some of the regulations promulgated so far have focused on controlling access rather than promoting it. It should be borne in mind that without access there can be no benefit-sharing. Such laws are generating high transaction expenses and a lot of red tape, and will curtail access applications in the long run. As long as the idea persists that access is a form of colonialism rather a mechanism that fosters team initiative and advantages for all the participants, the possibility of generating reasonable experiences will be limited. This is why, along with the necessary legal warranties, flexible and transparent regulation mechanisms are a *sine qua non*.

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3. El Salvador

Jorge Cabrera Medaglia

Legal aspects relating to genetic resources

Legal situation concerning genetic resources in the country

The use and exploitation of genetic resources are regulated by the Natural Environmental Law, Decree No. 233 of 4 March 1998, in the section on renewable natural resources and biological diversity. Factors concerning access to, manipulation of, research with and exploitation of biological resources are defined in Article 66. This article specifically indicates that

“the access, research, manipulation and exploitation of the biological diversity can only be carried out by means of a permit, licence or grant provided by the authority in charge of administering the resource, in order to ensure its protection and preservation in accordance with this law, with special laws, and with international conventions ratified by the country. When necessary, the local communities will be consulted prior to the provision of permits, licences or grants”.

This norm bestows each entity administering the resource with the jurisdiction to provide access, creating a system comprising various institutions that are responsible for access. To what extent this is beneficial is a question that should be pondered. It is evident that without due ruling, this general norm is barely effective. A rough draft of a by-law has been drawn up to regulate access to biochemical and genetic resources associated with wildlife. The Ministry of Environment and Natural Resources (MENR) will have exclusive authority to enforce this norm.

Likewise, in accordance with the Wildlife Conservation Law, Decree No. 844 of 14 April 1994 of 25 May 1994, it is declared that the wildlife forms part of the nation's natural heritage and as such its protection and management is to be assumed by the state (Article 3). It is important to highlight that this law should be interpreted in a broad sense on the understanding that it includes genetic resources (Salvadoran Environmental Law Foundation, 1997). It also regulates activities such as hunting, collection and trading, in addition to other forms of using and exploiting wildlife (Article 1). The National Park and Wildlife Service (PANAVIS), under the Ministry of Agriculture and Livestock, is the appropriate authority for issuing permits (at present, such authority is assigned to the Ministry of Environment and Natural Resources). The need to possess permits in order to collect wildlife for scientific purposes is established (Article 15).

Assuming that the wildlife's genetic resources form part of the natural heritage, the genetic resources included in the natural resources that are protected by the following laws should also be considered as part of the nation's natural heritage (Salvadoran Environmental Law Foundation, 1997).

The first article of the Forestry Law, Decree No. 852, states “... the forest resources are part of the nation's natural heritage and their protection and exploitation correspond to the state”. The General Law on Planning and Promotion of Fisheries Aquaculture, Official Journal Volume No. 353, 19 December 2001, states in Article 2 that “the hydrobiological resources found in jurisdictional waters form part of the national heritage. Such resources may be from the sea or from insular, continental or inland marine water organisms, or likewise from national waters and lands apt for aquaculture.” In view of these two dispositions, some have considered that the state has proprietorship over the aforesaid genetic resources (Salvadoran Environmental Law Foundation, 1997). Despite this assertion, it is evident that the state possesses a derived obligation to provide protection and guardianship, which entails the regulation of access thereto.

No specific dispositions exist with respect to the legal elements surrounding the country's genetic resources in indigenous, public and private lands. They are deduced from the fact that all the forestry, hydrobiological and remaining wildlife resources form part of the state heritage, the entity responsible for its protection and management. The people still have the power to authorize access to the genetic resources that are located on their lands or in the biological resources that contain them. Consequently, the controlling mechanisms are presently via the necessary PIC for the access to genetic resources, aside from the state's authorization.

Definition of genetic resources

The legal regimen of El Salvador defines genetic resources in different legislative bodies. Article 2 of the signed and ratified CBD, as published on 19 May 1994 in the Official Journal No. 92, Volume 3223, reads:

"Genetic resources are understood to be the genetic material of actual or potential value.

"Genetic material is understood to be all material of plant, animal or microbial origin or of another type that contains functional heredity structures; and

"'Biological resources' as being the genetic material of actual or potential value."

Article 2 of the Forestry Law, amended on 22 May 2002, Decree No. 852, refers to "genetic material as all material of plant, animal or microbial origin or of another type that contains functional heredity structures, and to 'biological resources' as being the genetic material of actual or potential value".

According to the Official Journal of 4 May 1998, Volume 339, No. 79, Article 5 of the Environmental Law defines genetic resources as "any material of plant, animal or microbial origin or of another type of actual or potential value that contains functional heredity structures".

The Central American Convention on Biodiversity, signed on 5 June 1992 during the XII Central American Presidential Summit in Managua, Nicaragua, and ratified by El Salvador, defines "genetic material as being any plant or animal material, microorganisms or of another origin, that contains functional structures containing hereditary information".

International legal obligations

Table 3.1 reflects the principal international agreements of interest in terms of genetic resources, ratified by El Salvador.

Table 3.1 Genetic resources-related agreements ratified by El Salvador.

International Agreements	Ratification
International Convention for Phytosanitary Protection (ICFP)	12 February 1953
International Undertaking on Plant Genetic Resources	Published in El Salvador's Official Journal on 7 March 1978; Agreement No. 762, of 21 December 1977
Convention establishing the World Intellectual Property Organization (WIPO)	18 September 1979
Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)	Decree No. 355, dated 16 May 1986, Official Journal No. 93, Volume 291 dated 23 May 1986
Convention on the Conservation of the Biodiversity and the Protection of Priority Wildlife Areas in Central America	19 May 1994
Paris Convention for the Protection of Intellectual Property	19 February 1994
Convention on Biological Diversity (CBD)	Official Journal No. 92, Volume 3223, of 19 May 1994
FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	9 May 2003, Published in the <i>Diario Oficial</i> No 83, Vol. 350.
WTO/TRIPS Agreements	7 May 1995
Cartagena Biosafety Protocol of the Convention on Biological Diversity, Montreal	Legislature on 23 April 2003 via Agreement No. 1224 and published in <i>Diario Oficial</i> No. 85, Volume 359 dated 13 May 2003

Policies and legislation to implement the obligations set out by the treaty

The following policy documents have been prepared and are related to the topic of access to biochemical and genetic resources.

The National Biodiversity Strategy is the instrument that gathers the objectives set out by the CBD and adapts them to the national reality. It confirms and adds a fourth objective relating to the evaluation and exploitation of biological resources in order to enhance a higher standard of living and development for the Salvadorans. The strategy has proposed a plan of action that identifies the priorities and the possible actors or participants in its execution.

MENR, as the environmental authority and in compliance with the Environmental Law, has made the following political proposals related to biological diversity:

- ***National Environmental Policy (implemented by MENR).*** Approved by the Council of Ministers on 21 September 2000, its objective is to harmonize economic growth with the protection of the natural resources and environment to improve the standard of living for all the country's inhabitants.
- ***Forestry Policy (proposed and under discussion).*** It promotes activities that would provide incentives in the private sector towards producing goods and services based on the exploitation of forest resources.
- ***Policy on Protected Natural Areas (implemented by MENR).*** Its objective is to consolidate the protected natural areas to conserve natural ecosystems, biological diversity, and ecological processes that regulate the environment. The focus is to study, preserve and diffuse knowledge, practices and traditional and new technologies that allow the preservation and exploitation of the biological diversity and bioexploration of the cultural, social-economic and physical aspects.
- ***Policy for Regulating the Use of Marine Coast Resources (DGRNR-MAG).*** Its aim is to modulate the exploitation and protection of the marine coast resources to improve the standard of living of the people.

- **National Science and Technology Policy (responsibility of the Ministry of Economy).** It is founded on the progressive improvement of the Salvadorans' standard of living as its fundamental core and focuses on sustaining of the natural resources and environment.
- **Policies and Programmes for Education (responsibility of the Ministry of Education).** The Ministry of Education under the educational reform process has modified the course syllabus in connection with the environment and natural resources. The policy is inclined towards environmental education as part of the national curriculum with a global concept of the environment as a multiple spectrum in all its components. Environmental education has also been adapted in the people's entire educational process in relation to their role and responsibility in conserving and developing natural resources to improve the community's environmental conditions.

The policy is also complemented with health science and environment as one of the principal curricular components by applying scientific observation and experimentation processes. This enhances the person's learning process, through reflection, and an analytical and critical attitude towards nature.

- **Protection of the TK and of farmers' rights.** No specific identified actions exist. Only 1% of the population is indigenous.

Regulations on access and benefit-sharing

Specific regulations, laws and policies on access to genetic resources

As mentioned previously, the Environmental Law, Decree 233 of 4 March 1998 contains a generic norm that states

"the access, research, manipulation and exploitation of the biological diversity can only be carried out with a permit, licence or concession provided by the authority in charge of administrating the resource, in order to ensure its protection and conservation in accordance with this law, with special laws and with international conventions ratified by the country. When necessary, the local communities are to be consulted prior to the provision of permits, licences or concessions" (Article 66).

Likewise, the Wildlife Conservation Law of 21 April 1994 regulates activities such as hunting, collection and trading, as well as other forms of use and exploitation of wildlife (Article 1). The competent body for giving out permits is the National Park and Wildlife Service of the Ministry of Agriculture and Livestock (at present MENR). The need to possess permits in order to collect wildlife for scientific purposes is established (Article 15). The law states that the wildlife forms part of the nation's national heritage and its protection and handling are to be assumed by the state (Article 3).

Existing institutional framework to control access

A Project on Enabling Activities of the Biodiversity was implemented in El Salvador. Its objectives include institutional support by the MENR (MENR, 1997) and establishing of technical procedures for access to the genetic resources associated with wildlife. This establishes that MENR is the competent authority for providing authorizations for access to genetic resources in the general management of natural heritage. Developing of the political elements and the strengthening of the ministry in terms of access to biochemical and genetic resources are additional components related to access to material (Table 3.2).

Article 66 of the Biodiversity Law sets out that the relevant permit, licence or authorization should be obtained from the authority responsible for the resource to be accessed. Therefore, in regard to agricultural resources or fishing resources the relevant governing bodies [Ministry of Agriculture (CENDEPESCA)] allow access thereto.

Nevertheless, there exists no established procedures except for genetic resources associated with wildlife.

Table 3.2 Summary of the principal legal and institutional framework regarding access.

Policy	Objective	Field of activity	Authority
Environment	Guide people on the quest for development.	Natural resources and environment	MENR
Forest	Develop the country's forestry.	Forest resources	Ministry of Agriculture and Livestock
Protected Natural Areas	Consolidate the protected natural areas.	Guarantee the conservation of biological diversity, ecosystems and ecological processes	MENR
Use of marine coastal resources	exploit and protect the marine coast resources.	Marine coast resources	CENDEPESCA – MAG
Science and technology	improve the Salvadorans' standard of living.	Natural resources and environment	Ministry of Economy
Programmes for Teaching Values	integrate the environmental theme in the entire educational process	—	Ministry of Education

Table 3.3 Summary of the legal framework for access to biochemical and genetic resources.

Law	Official Journal	Objective	Authority
Environmental Law Article 66	Volume 339, No. 79, 4 May 1994	protect, conserve and restore the environment and make use of the natural resources	MENR
Wildlife Conservation Law	Volume 352, No. 133, 16 July 2001	protect, restore, handle, exploit and conserve wildlife	MENR
Forestry Law	Legislative Decree, No. 852, 22 May 2002	increase, exploit and use forest resources	Ministry of Agriculture and Livestock
Law of Vegetable and Animal Health	Volume 329, No. 234, 18 December 1995	protect vegetable and animal health in harmony with the natural resources	Ministry of Agriculture and Livestock
Seed Law	Legislative Decree No. 530, 30 August 2001	guarantee the identity, genetic purity and physical, physiological and health quality of seeds, and their research and production.	Ministry of Agriculture and Livestock
General Law for Legislation and Promotion of Fisheries Aquaculture	Volume No. 353, 19 December 2001	regulate legislation and promotion of fisheries and aquaculture activities, and ensure the conservation and development of hydrobiological resources.	Ministry of Agriculture and Livestock
Special Law on Protection of El Salvador's Cultural Heritage	No. 68, Volume 331, 15 April 1996	regulate the rescue, research, conservation, protection, promotion, development, diffusion and evaluation of Salvadoran cultural heritage.	Ministry of Education
National Board of Science and Technology Law	Decree No. 287, 17 December 1992	formulate and direct national policy in matters relating to technological and scientific development.	Ministry of Economy
Law on Development and Protection of Intellectual Property	Official Journal No. 150, Volume 320, 16 August 1993	regulate aspects related to intellectual property and protection	Home Office
General Regulation of Environmental Law	Executive Decree No. 17, 21 March 2000	develop the norms and provisions contained in the Environmental Law	MENR

Legal framework on access to and benefit-sharing from biochemical and genetic resources

The applicable laws and decrees are summarized in Table 3.3.

Environmental Law

Legislative Decree No. 239, published in the Official Journal, Volume 339, No. 79, aims to develop the dispositions of the National Constitution that refer to the protection, conservation and recovery of the environment and the use of natural resources to improve the standard of living for present and future generations.

It establishes regulations for private and public environmental protection as a basic obligation of the state, municipalities and inhabitants in general, and ensures that international agreements and treaties are enforced in El Salvador.

Article 66 of the law states:

“the access to, and the research, manipulation and exploitation of the biological diversity, may only be brought about through the relevant permit, licence or concession provided by the authority in charge of administrating the resource, in order to safeguard its protection and conservation in accordance with this law and the international conventions and special laws ratified by the country. When necessary the local communities are to be consulted, prior to the provision of permits, licences or concessions.”

Article 21 of the law adds that “all natural or juridical persons should present the relevant Environmental Impact Assessment in order to execute the following activities, works or projects ...”, specifying the “biotechnological industries or projects or those that imply the genetic handling or production of genetically modified organisms”. Article 22 indicates that the proprietors of the activities indicated in Article 21 that require an environmental permit should submit to the ministry the corresponding environmental form for approval.

Furthermore, it is important to point out that only Article 68 of the Environmental Law, in the Security Norms concerning Biotechnology, expresses that the ministry backed by the specialized institutions, will implement the security norms that are to be abided by the resulting human action via the biotechnology, supervising its employees, with the aim of minimizing adverse impact on native biological diversity.

General Regulation on the Environmental Law

Executive Decree No. 17 of 21 March 2000

The objective of the general regulation is to develop the norms and precepts contained within the Environmental Law, to which it is adhered as its principal enforcing instrument. Article 3 names MENR as the competent authority for implementing the dispositions set out in the regulation.

Article 79 establishes that the ministry, by virtue of its decree of creation, and of the attributions bestowed upon it by the Governing Body’s Internal Regulation and Article 65 of the Law, is the authority responsible for ensuring that in the permits, licences and concessions regarding the use and exploitation of the natural resources, sustainability is guaranteed.

Likewise, Article 20 of the regulation indicates that the proprietor of the activities, works or projects according to Article 21 of the Environmental Law, requires an environmental permit to be submitted to the ministry, providing the information sought through the environmental form. The ministry should decide, within 20 days, and based on the information provided, whether an evaluation of the environmental impact is called for prior to the granting of the environmental permit (Article 22 of the Regulation). Should it not be required, the applicant will receive the environmental permit. In the same manner, Chapter

II of the regulation establishes the requirements for approval of the evaluation of environmental impact.

Article 91 indicates the conservation of the autochthonous biotic areas to ensure the continuity of the evolutionary processes, including the animal migrations and the patterns of genetic flow. Based on Article 92, the ministry, in conjunction with the competent authorities, should maintain examples of the different characteristics of each type of community, landscape and form of national geological land, with the aim of protecting the country's utmost unique and representative diversity.

The aforementioned is complemented with the contents of Article 93 relating to the conservation of genetic heritage, as the foundation of national natural heritage and that, in conjunction with the competent authorities, it should ensure a group of areas, that are capable of functioning as the country's genetic reserve banks.

Wildlife Conservation Law

Revised by Legislative Decree No. 441, published in the Official Journal No. 133, Volume No. 352 of 16 July 2001

The aim of this law is to protect, restore, handle, exploit and conserve wildlife. This includes the regulation of activities such as hunting, harvesting and trading, in addition to other forms of use and exploitation of this resource. The same law defines wildlife as referring to the species of biological diversity that live and reproduce independently from man's influence, as well as those species introduced into the country that manage to establish free reproductive populations, be they land, aquatic or aerial, resident or migratory, and the parts and products derived therefrom, except for the species of animals or plants, domestic or agricultural, livestock or fish, always provided that these rely upon man in order to survive.

With regard to the protection, use and exploitation of wildlife, Article 8 states:

"all use of the wildlife, including the hunting, reproduction, importation, exportation, re-exportation, harvesting and possession for any purpose, will be ruled by the corresponding regulations and dictated by MENR, in conjunction with the relevant institutions or bodies".

Forestry Law

Decree No. 852 of 22 May 2002.

The present law impels, promotes and supports the participation of private companies, creating a Forestry Commission made up of representatives from the forestry sector and government, which will safeguard the industrial and technological development of forest resources, incentives and other activities that aim towards the recovery and exploitation of tree coverage within the national territory.

The purpose of this law is to establish dispositions that permit the increase, handling and exploitation of forest resources, develop the timber industry; and aims to stimulate private sector participation in the reforestation of the national territory for productive purposes. The Salt Forests and Protected Natural Areas are excluded from this regulation.

Other policies, laws and regulations with an impact (direct or indirect) on access and benefit-sharing of genetic resources

Principal components of the relevant laws and their potential impact

Law of Vegetable and Animal Health

Decree Law No. 524, published in the Official Journal Volume 329, No. 234 of 18 December 1995.

This law is considered to be linked with the protection of the environment, natural resources and human health by activities that are developed in the farming sector and particularly with the measures of prevention, control and eradication of plagues and diseases in plants and animals that affect national production. The law seeks to establish the dispositions towards the sanitary protection of plants and animals and that all the actions that emanate from the law should be in harmony with natural resources, and protection of the environment and human health.

This legal instrument does not make reference to access to genetic resources. Its relevance derives from the registration and control of importation and exportation of goods and supervision, inspection and certification of the phytosanitary condition of crops, nurseries and means of transport for plants. In the area of animal health, it serves to identify and diagnose pests or diseases that affect the production, commerce and transport of animals. Its link is present through the samples of plants or animals for export or import and with supervision and control of the sanitary conditions of these resources. At the end, a health certificate is issued that attests to the state of health of the goods exported, thereby preventing diseases and pests from spreading to other countries. The same applies once the access permit has been obtained and the samples of biological material are intended for export.

Seed Law

Legislative Decree No. 530 of 30 August 2001, Official Journal

Agriculture is one of the principal elements of the country's economy. It is therefore worth offering incentives to encourage the research, production, commercialization and employment of improved seeds of optimum quality in order to increase productivity. This activity should be in accordance with international trade policies that guarantee favourable conditions for the investigation, production, commercialization and importation of seeds.

The aim of this law is to establish legislative standards that guarantee the identity and genetic purity, physical, physiological and sanitary quality of the seeds, and associated research, production and commercialization.

There is no reference to any specific article in relation to the procedure of access to the genetic resource. Instead it is more inclined towards the commercialization and importation of seeds. Article 30 "Transitory Dispositions" prohibits the importation, investigation, production and commercialization of transgenic seeds, which to some degree slows down biotechnological activities in the country. Initially, access to genetic resources for use in a biotechnology context would be prevented (Figure 3.1). Practical application is not verified insomuch as it refers to the release in the field or the commercialization of transgenic seeds, despite the terms set out by the law. Nevertheless, El Salvador's ratification of the Protocol of Cartagena can be interpreted as an annulment of such prohibition.

Figure 3.1. Technical administrative procedures for access to biochemical and genetic resources associated with wildlife for industrial purposes in compliance with the draft regulation. The governing authority is the General Directorate for Heritage Management

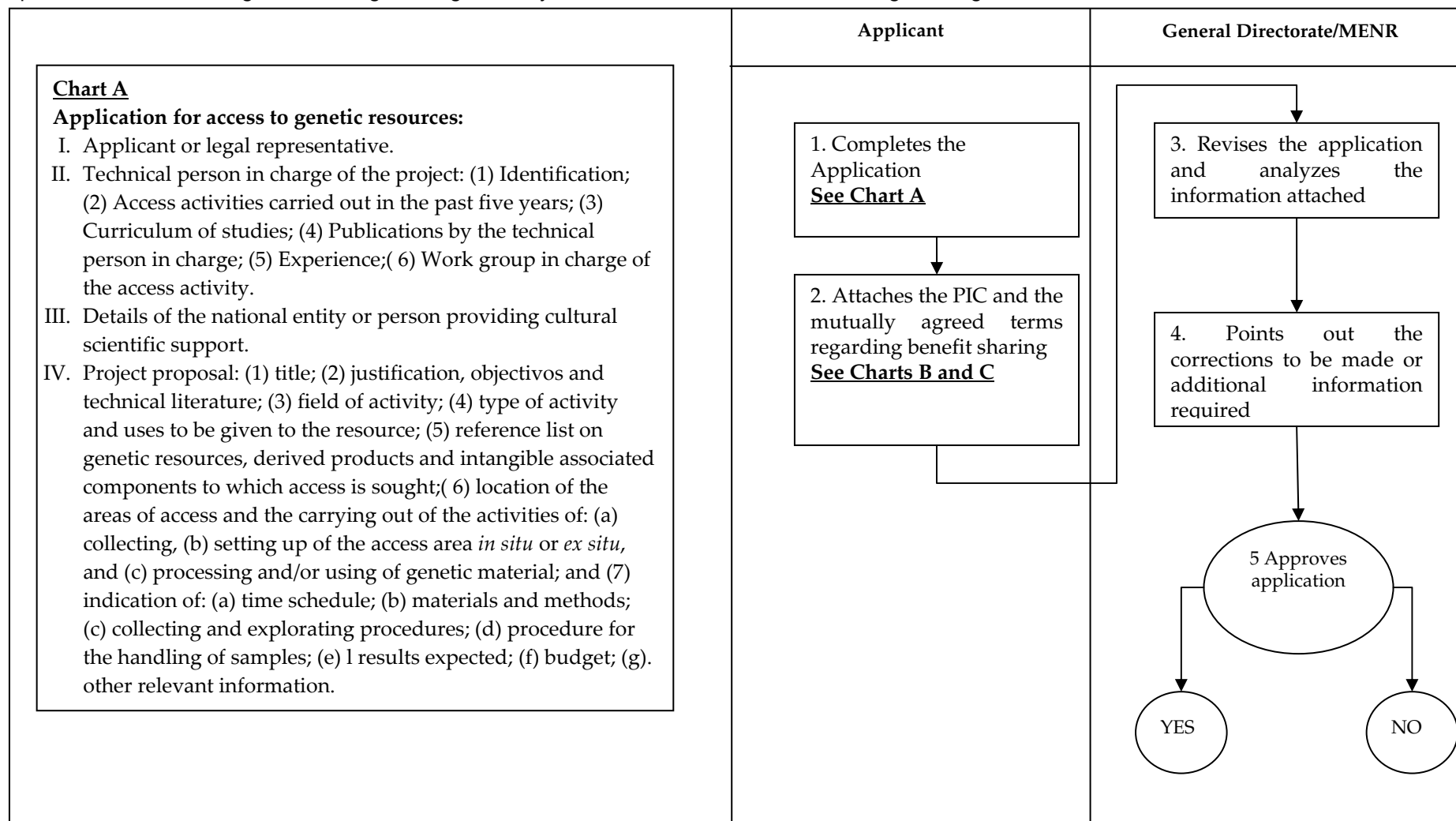


Chart B

Procedure to obtain the ROBERT PLEASE PROVIDE IN FULL (CIP):

- I. Applicant's affiliation, and legal entity
- II. Type and quantity of genetic resources
- III. Date of commencement and duration of the activity
- IV. Geographical exploration areas
- V. Information relating to the use planned
- VI. Determination of the onset of the research and development.
- VII. Manner in which the research and development is carried out.
- VIII. Local bodies that collaborate in the research and development.
- IX. Possible intervention by third parties.
- X. Objective of the collection, research and results envisaged.
- XI. Classes and types of benefits that could be derived from the access, including commercial use and others
- XII. Indication of agreement concerning benefits.
- XIII. Budget.

Note: when handling confidential information in the case of TK, get permit or authorization from the authority designated by the indigenous community..The corresponding authority may call for EIA in a given case.

Applicant

Exceptions:

- Genetic components or parts of human beings
- The exchange of biological resources brought about by local or indigenous communities amongst themselves for their own purposes and based on ancestral practices

Should request the relevant permits from the corresponding authority depending on the resource:

- Environmental Law and its regulation
- Forestry Law
- General Law of Ordinances and Promotion of Fisheries and Aquaculture
- CITES
- Wildlife Conservation Law

8

General Management/DENR

YES

6. Gives its preliminary approval. Calls for a contract to be drawn up between the applicant and the DENR
See Chart D

7. Negotiation of the terms and clauses of the contract
See Chart D

NO

6.1 Considers it to be inadmissible through a duly well-founded

7.1 The applicant is notified in order that he/she may lodge the relevant administrative or judicial appeal.

10

Chart C Agreements of mutual accord should contain:

(a) quantity of samples that may be obtained and eventually exported; (b) obligations relative to exclusiveness; (c) the obligation of ensuring that the activities of access do not cause genetic erosion or deteriorate or negatively affect the ecosystems and species; (d) terms, conditions and restrictions under which the transfer of material to third parties, and the obligations acquired by such third parties is to be permitted; (e) dispositions regarding intellectual property rights, including the possibility of joint ownership of intellectual property rights, according to the level of contribution and the origin of the licences; (f) obligations relating to the profit-sharing of the economic and financial benefits, including the payment of bonuses or milestone payments for samples and payments of research budgets, according to the nature of each specific case; (g) supply of information regarding antecedents, the state of the science or other details that contribute towards improving the knowledge of the resources and the biodiversity in general; (h) obligations regarding non-monetary profit-sharing such as the transfer of technology, research, and training and educational programs; (i) obligations concerning the filing of duplicates of all material gathered institutions appointed by the MENR for these purposes, when necessary; (j) clauses referring to the use of the results derived from the research in preferential conditions, when relevant, under the appropriate conditions; (k) clauses that guarantee the contracting party's future supply of larger quantities of biochemical and genetic resources, should this be required in order to continue with the research and development process; (l) dispositions relating to the availability of the results of the research carried out; (m) dispositions regarding a national counterpart or institution's participation in the collection, research and development of products, when relevant; (n) commitment to comply with the environmental regulations, including the norms concerning biosafety and sanitary and phytosanitary measures that are applicable; (ñ) motives for terminating the contract and mechanisms for resolving controversies. It should be stated that the non-compliance of the conditions under which the access was provided constitutes grounds for cancellation of the access contract in favour of the DENR and the supplier depending on the case; (o) formalities and conditions for controlling and monitoring compliance with obligations relating to access; (p) end of the agreement and possibilities of renewal; (q) formalities in which the activities will contribute towards the conservation of species and ecosystems; and (r) any other disposition to be negotiated in each particular case.

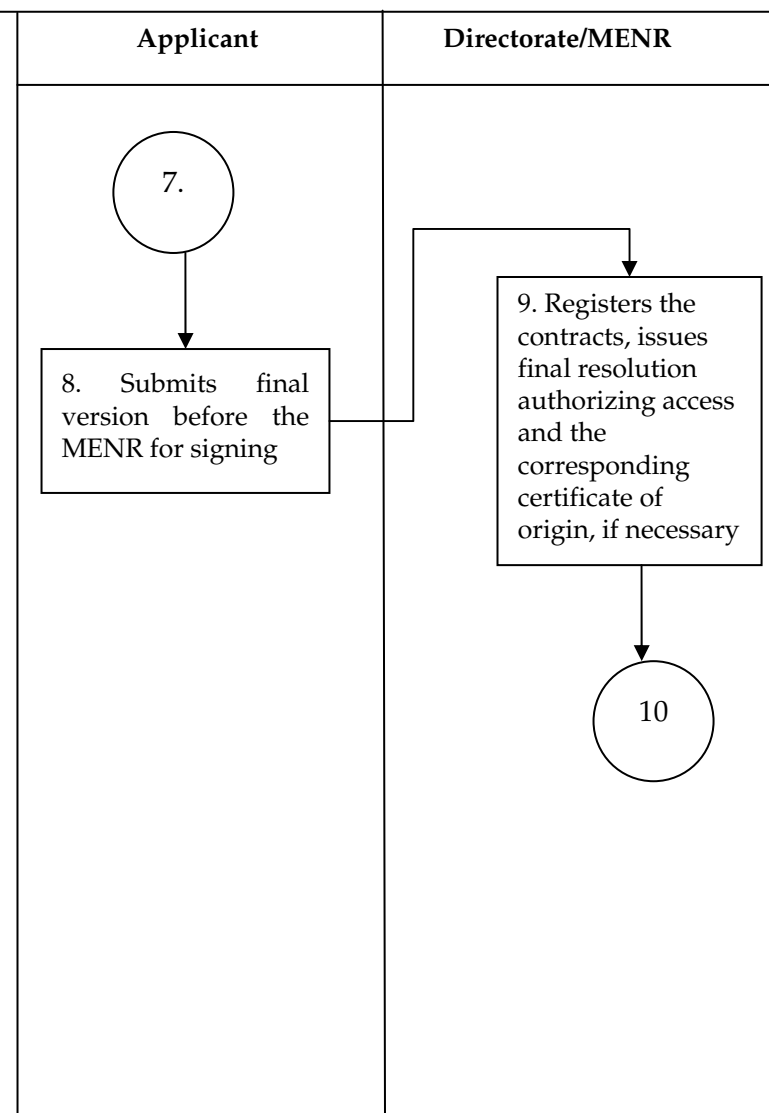


Chart D

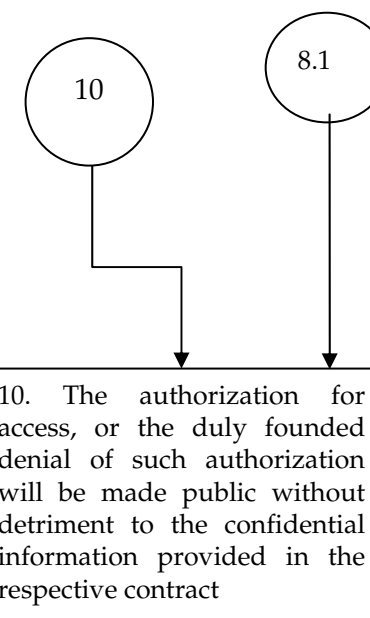
Access contract

The parties may comprise the: (a) state, represented by the relevant governing authority; (b) the applicant seeking the access; (c) access agency or office; (d) supplier of the knowledge associated with the resource, in those cases in which these components are involved; (e) community, when an application for access involves TK of a farm crop (ruled by the CENTA and the FAO Convention); and (f) private or public institution that serves as national support, in which case a related contract should be required by the corresponding authority.

It should contain the: (a) definition of the objective; (b) determination of the proprietorship of eventual IPR and the commercialising of goods or processes obtained and conditions for the concession of licences; (c) access agency or applicant's obligation to not assign or transfer the access, handling or use of the genetic resources or their derived products to third parties without specific consent from the corresponding Principal Authority (PA) or from the local community or indigenous peoples that hold the TK and object of the access procedure; (d) applicant's commitment to inform the Corresponding Authority (CA) of the research and uses of the genetic resources and products derived from the resource object of the access; (e) applicant's commitment to provide the CA with the publications produced; advising on the attainment of processes or products that are new or different to those stated in the contract, and request the CA to provide authorization for the transfer or movement of genetic resources or products derived from areas outside the ones designated for the access procedure. (f) commitments of confidentiality.; (g) obligation to deposit samples of genetic resources and products derived from the access, including all associated material, at institutions appointed by the CA, with the express prohibition of being taken out of the country; (h) schedule of regular updates on results obtained to the CA; (i) guarantees that ensure indemnification and clauses relating to compensation for non-compliance of the contract or for harming the environment; and (j) compliance to all the other national norms, particularly s with respect to health control, biosecurity, and environment protection. The access contract will remain in force throughout the term that is to be determined by the CA; it can be renewed.

Applicant

General Management/ DENR



General Law for Legislation and Promotion of Fisheries and Aquaculture

Official Journal, Volume No. 353 of 19 December 2001

Its aim is to regulate and promote capture fishery and aquaculture activities, ensuring the sustainable development and conservation of hydrobiological resources.

The Law adopts a series of concepts and measures that tend towards the conservation of the resource, including:

- It is stated that the national heritage includes hydrobiological resources that are found in jurisdictional waters, be they in the sea or as bodies in insular, continental and interior natural waters, as well as in national waters and lands that are apt for aquaculture.
- The sustainable development and protection of hydrobiological resources are declared to be of social interest.
- The precautionary principle is set forth, that consists of establishing temporary ordinance measures when scientific information is not available.
- Aquatic reserve areas are defined as those natural places that are favourable for the reproduction or habitat of species, where it is advantageous to establish systems of protection and conservation. According to the law, such places are the river mouths of Garita Palmera, Barra de Santiago and Cordoncillo, the outlet of the River Lempa and the Bay of Jiquillisco, covering to an area of 1.5 miles on each side of the central point of the river mouth and 3 miles out to sea.

The law defines hydrobiological organisms as all animal or plant organisms whose natural living environment is the water. This definition also includes species such as whales, dolphins and turtles. In order to conduct scientific fishing, which the law itself defines as “that which is conducted for the purpose of investigation, experimentation, restocking and conservation, evaluation of the hydrobiological resources or the collection of live samples intended for adornment, aquariums, zoos, maintenance and replacement of cultural or scientific collections and the unfolding of new technology.” it is necessary to acquire permits or licences from CENDEPESCA.

It has no direct impact in Figure 3.1, as the access procedure is carried out in connection with genetic resources associated solely with wildlife.

Special Law on Protection of El Salvador’s Cultural Heritage

Decree No. 513 of 28 March 1996, published in the Official Journal No. 68, Volume 331 of 15 April 1996.

This law aims to regulate the rescue, investigation, conservation, protection, promotion, development, diffusion and evaluation of the Salvadoran cultural treasury or heritage, through the Ministry of Education or the Secretariat of State responsible for administrating the country’s cultural heritage.

Article 2 defines the concept of cultural assets as “those that have been specifically acknowledged by the ministry, be they of an anthropological, paleontological, archaeological, prehistoric, historic, ethnographic, religious, artistic, technical, scientific, philosophical, bibliographical or documentary nature”.

The same law defines the concept of assets that conform to the cultural heritage, that in the interests of protection and conservation of biodiversity in *ex situ* collections, recognizes the following as Assets: zoological, botanical, mineralogical, anatomical collections and specimens, and objects of paleontological interest; assets of historical significance, including history of science; and old publications of special historic, artistic, scientific and literary

interest that could be of historic or TK significance associated with the genetic resources or the country's biodiversity.

It has no direct impact on the access procedure.

Law on National Science and Technology

Decree No. 287, 17 December 1992.

The principal aim of the law is to form and direct national policy in matters relating to technological and scientific development, towards the country's socio-economic development. It does not address biological diversity nor does it mention anything in connection with enhancing biotechnology in El Salvador.

It has no direct impact on the access procedure.

Other normative laws

Other items affect the legal framework for sustainable use of biodiversity. The following are worth noting as they create protected wildlife areas in El Salvador:

- Executive Decree No. 53, issued on 17 November 1987 published in the Official Journal No. 212, Volume 297 on 18 November 1987, which establishes the 'Montecristo' National Park.
- Executive Decree No. 20, issued on 17 March 1989 published in the Official Journal No. 103, Volume 303 on 6 June 1989, which establishes the 'El Imposible' National Park.
- Executive Decree No. 59, issued on 22 August 1986 published in the Official Journal No. 154, Volume 292, of the same date, that contains the forestry prohibition in the region of the 'El Imposible' Forest.
- Executive Decree No. 14, issued on 1 April 1986, published in the Official Journal No. 56, Volume 296 of the same date, that contains the regulation for the establishment of salt mines and exploitations with the aim of marine aquaculture of salt forests.
- Legislative Decree No. 689, approved on 18 April 1996, published in the Official Journal No. 101, Volume 331 of 3 June of the same year, that contains the Declaration of the Protected Natural Area 'La Laguna El Jocotal'.
- Decree Law No. 885 of 13 April 2000 published in the Official Journal No. 79, Volume 347 on 28 of the same month and year, by means of which the San Lorenzo ranch situated in the city of Santa Ana, was declared a Protected Natural Area.

Intellectual property system

The Intellectual Property Protection Law of 1993 does not specifically exclude from patenting plant varieties, or essentially biological processes for the attainment thereof (Article 107). Additionally, Article 5 of the Seed Law establishes that no official institute, autonomous institute or state organ devoted to research and production of seeds may deny access to duly registered individuals or companies from the private sector to the products of their own registered investigations, which in any case will not have an exclusive nature, nor may they be granted with that characteristic to those persons. The official institute, autonomous institute or state organ, proprietor of the rights or plant varieties, should establish the conditions under which such products achieved from research may be transferred to individuals (Article 5).

Therefore, upon allowing a plant variety's protection through this mechanism the patent requirements should be met, namely, industrial application, novelty and inventive step (Article 111). These requirements are more difficult to satisfy than the requirements set out in the laws on varieties (stability, homogeneity, novelty and distinctness) and by which certain

“phytogenetic creations” may possibly not satisfy the requirement relating to the inventive step, or perhaps not be new (in the sense of the patent law).

The rights conceded are greater and intended

“to prevent third parties from conducting the following acts without prior consent when the patent has been granted:

- (a) for manufacture, sale, use and import of the product, or storage for any of these purposes; or
- (b) to employ or execute the procedure or any of the actions indicated on point (a), with respect to a product obtained directly from the procedure” (Article 115).

There do not exist special limitations or exceptions in the case of patents that make use of the biological material. The exceptions refer to activities in private fields and without commercial purposes, with the aim of research and teaching, and the exhaustion of the rights once the product has been commercialized for the first time in a legal manner (Article 116). The possibility of complementing the deposit of biological material is contemplated, such action being effected at a deposit institute that complies with the requirements set out under the law’s regulation (Article 138).

The patent will have a legal life of 20 years calculated from the application date and of 15 years in the case of medicines (Article 109). The law also regulates trade or industrial secrets under the usual terms (Articles 177 *et seq.*). With regard to the protection of the rights corresponding to the plant varieties, El Salvador does not recognize such rights specifically. However, patent applications have been filed in the past for certain varieties, such as vetiver, based on the Intellectual Property Protection Law.

New initiatives relating to access and benefit-sharing of genetic resources

The Project on ‘Biodiversity’s Enabling Activities’ within MENR is to generate the basic conditions to comply with the CBD. An access component is included for the genetic resources associated with wildlife, proposing clear access procedures to current and potential users of the biochemical and genetic resources associated with wildlife. The policy guidelines proposal regarding access to El Salvador’s biochemical and genetic resources aim to create adequate conditions on use and fair and equitable sharing of the benefits derived from this use.

The proposed policy guidelines take into consideration the country’s current state of biodiversity, national regulatory framework and binding international conventions. In addition, it also underlines the objectives and principles of the National Policy on access to biochemical and genetic resources.

The methodology employed consisted of compiling and revising relevant information at a national and international level, especially regarding the experiences developed by other countries. Research was conducted from documents related with general orientations and reference frameworks for the establishment of regulatory conditions of access to genetic resources.

Finally, experts were consulted in order to exchange specific ideas and experiences on the national reality, identifying the actual use and potentialities of exploiting the biochemical and genetic resources associated with wildlife.

The draft regulation on access

The instrument aims to regulate access to the biochemical and genetic resources associated with wildlife in El Salvador, with the purpose of:

- ensuring the conservation of the biological diversity and use of its components as a mechanism to maintain and improve the peoples' quality of life;
- establishing an appropriate system of access to the biochemical and genetic resources based on the PIC and mutually agreed terms;
- ensuring fair and equitable sharing of the benefits derived from the access to the biochemical and genetic resources;
- providing a transparent framework to facilitate the access to the biochemical and genetic resources associated with wildlife;
- ensuring the creation and development of scientific, technical and technological capacities at local and national levels concerning the use of their biochemical and genetic resources;
- promoting the transfer of appropriate technology for the suppliers of biochemical and genetic resources and the state as supplier of the resources;
- strengthening of El Salvador's negotiating capacity at the conventions or in contracts related to access to biochemical and genetic resources and the sharing of benefits; and
- providing a mechanism for access to biological resources using TK.

These procedures are to be applied to the biochemical and genetic resources associated with wildlife that are found under the state's sovereignty, irrespective of whether *in situ* or *ex situ*.

- The following are excluded from the scope of applicability:
- genetic components, parts or totalities of human beings, without detriment to the existing sectoral regulations;
- exchange of biochemical and genetic resources associated with wildlife and the associated TK brought by the local communities for their own purposes and based on their customary law practices;
- access to and use of biological resources distinct from their use as a source of biochemical and genetic resources;
- access to biochemical and genetic resources included in ITPGRFA, as they may be included in this instrument; and
- investigating for inventory, systematics or taxonomic purposes.

The Department of Environment and Natural Resources (DENR), General Management of Natural Heritage, is the competent authority. It provides authorizations for access to biochemical and genetic resources and is the governing body responsible for dictating general norms and policies for the access. The competent authority may designate ad hoc committees of an advisory nature or request advice from an individual, corporate, public, private or international institution, depending on the circumstances.

The responsibility of the users or applicants would be to:

- fully carry out their responsibilities in a clear, objective and transparent manner;
- request authorization from the DENR prior to carrying out the activities that the access to the biochemical and genetic resources entails;
- use the biochemical and genetic resources only for those purposes that are set out under the terms and conditions of access as acquired;
- obtain a new PIC and arrange mutually agreed conditions to use biochemical and genetic resources for purposes other than those for which were acquired;
- respect all the terms and conditions relating to the materials acquired and the obligations or restrictions established for such transfer by the DENR in supplying third parties with biochemical and genetic resources;

- conserve all the details relating to the biochemical and genetic resources, particularly documented evidence of the PIC, origin and use of the genetic resources and derived benefits of its use;
- use the biochemical and genetic resources, to the greatest degree possible, within the national territory and with the participation of national investigators; and
- comply with the mutually agreed conditions that were arranged with the interested parties, to guarantee the equitable and fair sharing of the derived benefits, including the transfer of technology to the country.

The suppliers also have the responsibility to:

- only provide biochemical and genetic resources associated with wildlife and the associated TK, when they have the right to do so in accordance with the national legislation; and
- avoid imposing unnecessary restrictions on access to biochemical and genetic resources.
- The state, as the supplier, should also comply with these conditions.

Access to biochemical and genetic resources associated with wildlife will be subject to PIC and existence of MAT between the applicant and DENR. The state, through DENR, will authorize the corresponding access and will conclude an access contract with the applicant.

The procedure for access to biochemical and genetic resources begins with the completed application by the applicant, be it an individual, corporate, national or foreign body. The respective procedure should be completed and the access contract between the DENR and the interested party signed. Before signing the contract, any access to the biochemical and genetic resources will be regarded as illegal and not sanctioned in compliance with the laws of the country.

There are regulations on the requirements for access to biochemical and genetic resources for industrial purposes (Article 13), for academic purposes (Article 14), with different procedures for each (Article 15). Likewise, there are regulations for authorizations for access in *ex situ* conservation centres (Article 16). Article 17 establishes the minimum aspects of discussion between the parties in order for the supplier to provide PIC and to negotiate the MAT of benefit-sharing.

In the case of local communities, additionally, and depending on the circumstances of the case, the development of an identification process will be required. The aforesaid communities need to be consulted regarding the scope and consequences of the access.

The contracts for MAT on benefit-sharing for both the suppliers and DENR should contain:

- quantification of samples that may be obtained and eventually exported;
- obligations relating to exclusivity;
- a guarantee that the activities of access do not cause genetic erosion, deterioration or negatively affect the ecosystem and species;
- terms, conditions and restrictions under which the transfer of the material to third parties; and the obligations acquired by the latter, will be permitted;
- dispositions concerning IPRs, including the possibility of joint ownership of the IPRs;
- obligations referring to financial and economic benefit-sharing, including commissions, milestone payments, payments for samples and investigation estimates, depending on the nature of each particular case;
- information on antecedents, the state of the science and other details that contribute towards improving the knowledge of the resources and the biodiversity in general;

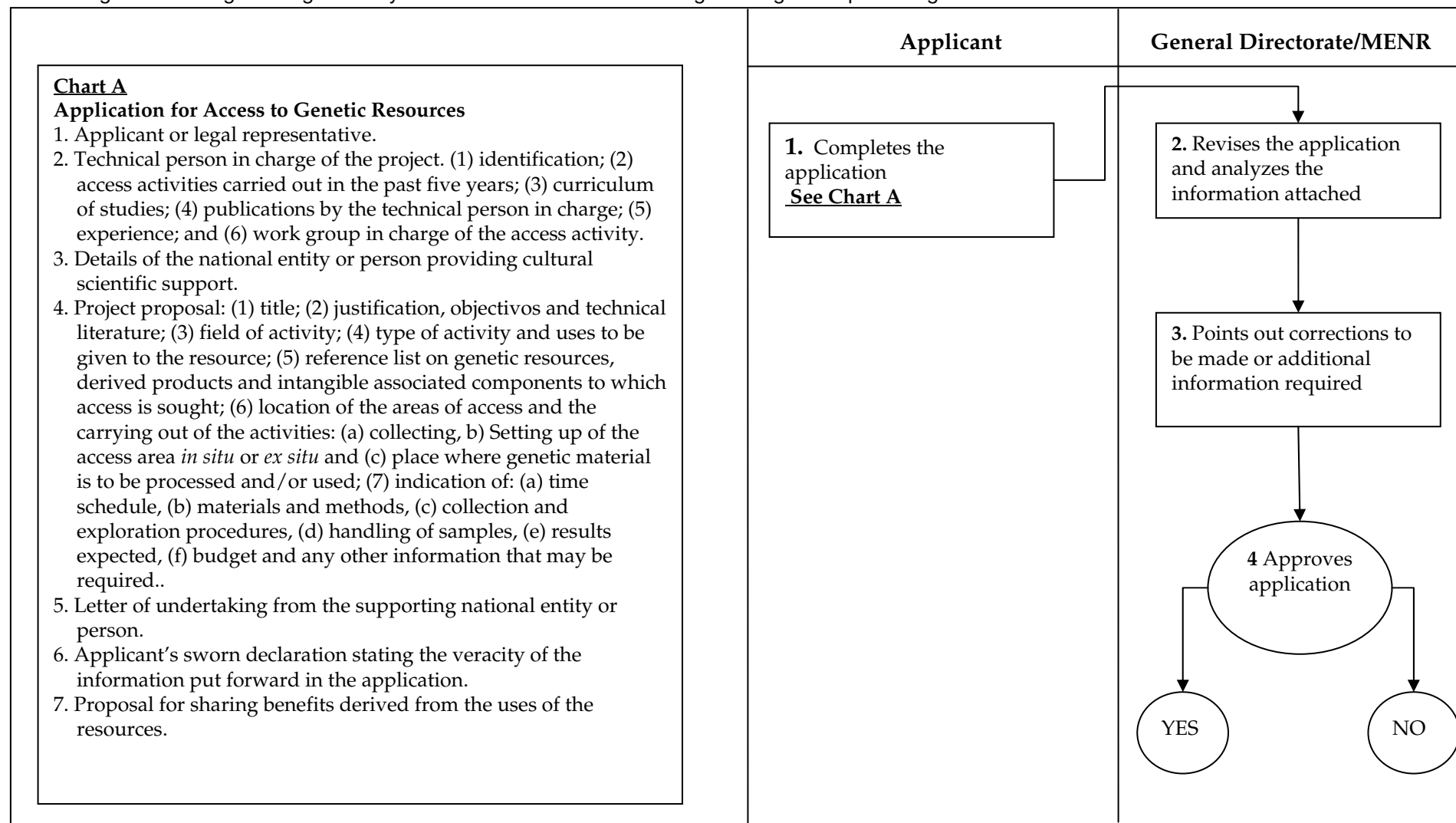
- obligations referring to the sharing of non-monetary benefits such as the transfer of technology, investigation, and training and educational programmes;
- obligations regarding the filing of duplicates of all material gathered in institutions appointed by the MENR for such purposes, when applicable;
- clauses referring to the use in preferential conditions, when applicable to the results derived from the investigations under the appropriate conditions;
- clauses that guarantee the contractor's future supply of larger quantities of biochemical and genetic resources, should these prove necessary in order to continue with the process of investigation and development;
- dispositions related to the availability of the results of the investigations conducted and concerning participation in the collection, investigation and development of products with a national counterpart or institution, when relevant;
- the commitment to comply with the environmental regulations, including the applicable rules governing phytosanitary, sanitary and biosafety measures;
- conditions for terminating the contract and mechanisms for resolving controversies. It should be established that the non-compliance of the conditions under which the access was provided constitutes grounds for cancellation of the contract of access in favour of MENR or the supplier, depending on circumstances;
- formalities and conditions to control and monitor the fulfilment of the obligations related to access;
- duration of the agreement and possibilities of renewal;
- formalities in which the activities will contribute to the conservation of the species and ecosystems; and
- any other disposition to be negotiated in each particular case.

MENR may impose partial or total restrictions on access to the biochemical and genetic resources to ensure their conservation and use (Article 19). The information contained in the access contracts and applications will be of free access to the public (Article 21). Furthermore, agreements can be reached for standards of access for research or teaching with universities, or centres of investigation that protect the execution of various projects, with the aim of facilitating access to biochemical and genetic resources (Article 23). Subsequently, in conjunction with the rest of the suppliers and the national counterpart, if one exists, in accordance with the commitments established in the contract of access to biochemical and genetic resources, the relevant verification and control tasks will be carried out (Article 28).

The non-compliance of the agreements and commitments will result in the cancellation of the contract of access to biochemical and genetic resources and to the annulment of the resolution that granted the permit and issued the certificate of origin (Article 28).

Illustrations on the decision-making process on access to genetic resources

Figure 3.2. Technical administrative procedures for access to wildlife-related biochemical and genetic resources for academic purposes based on draft of access regulation. The governing authority is General Directorate for Heritage Management pertaining to MENR.



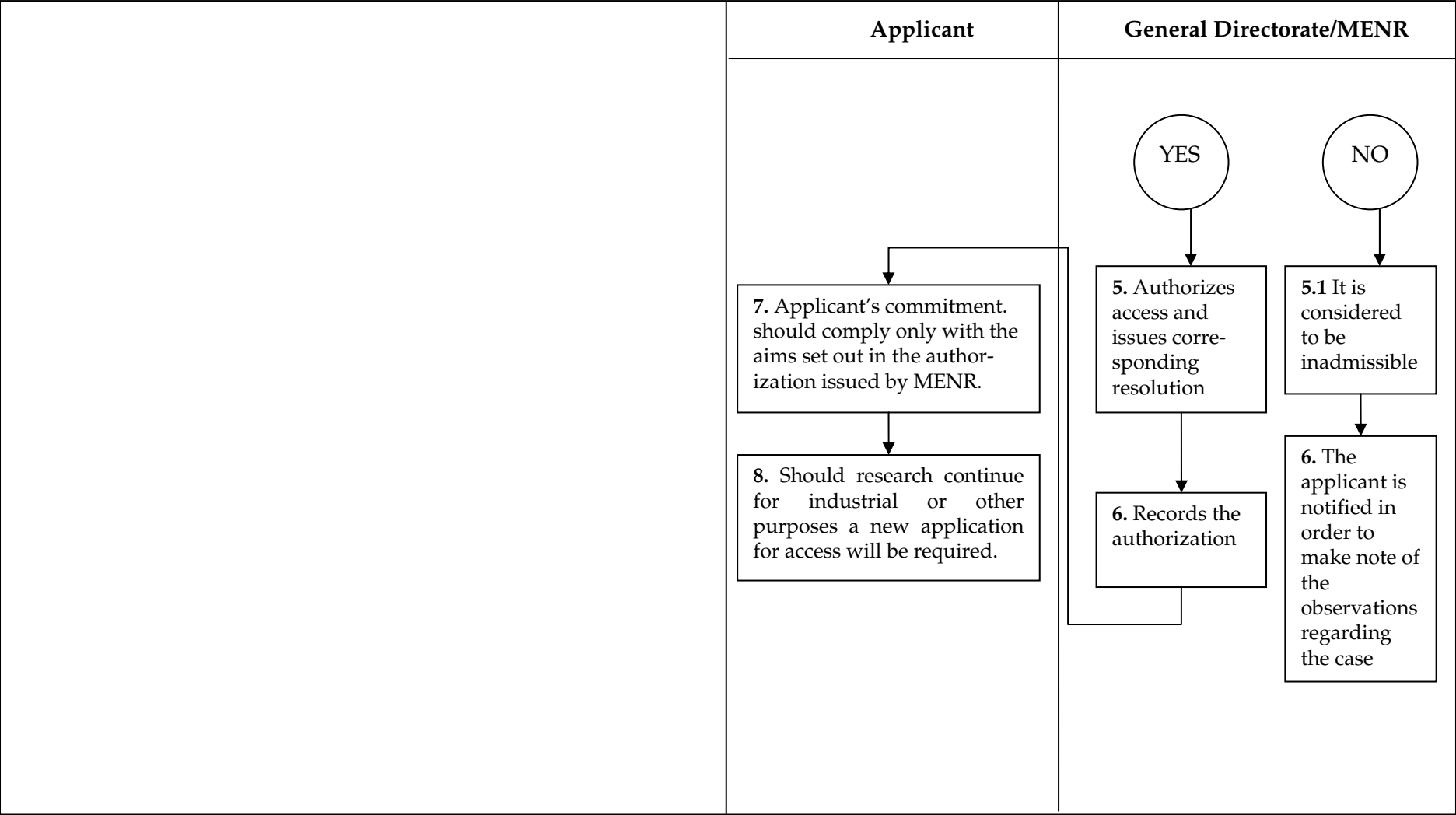
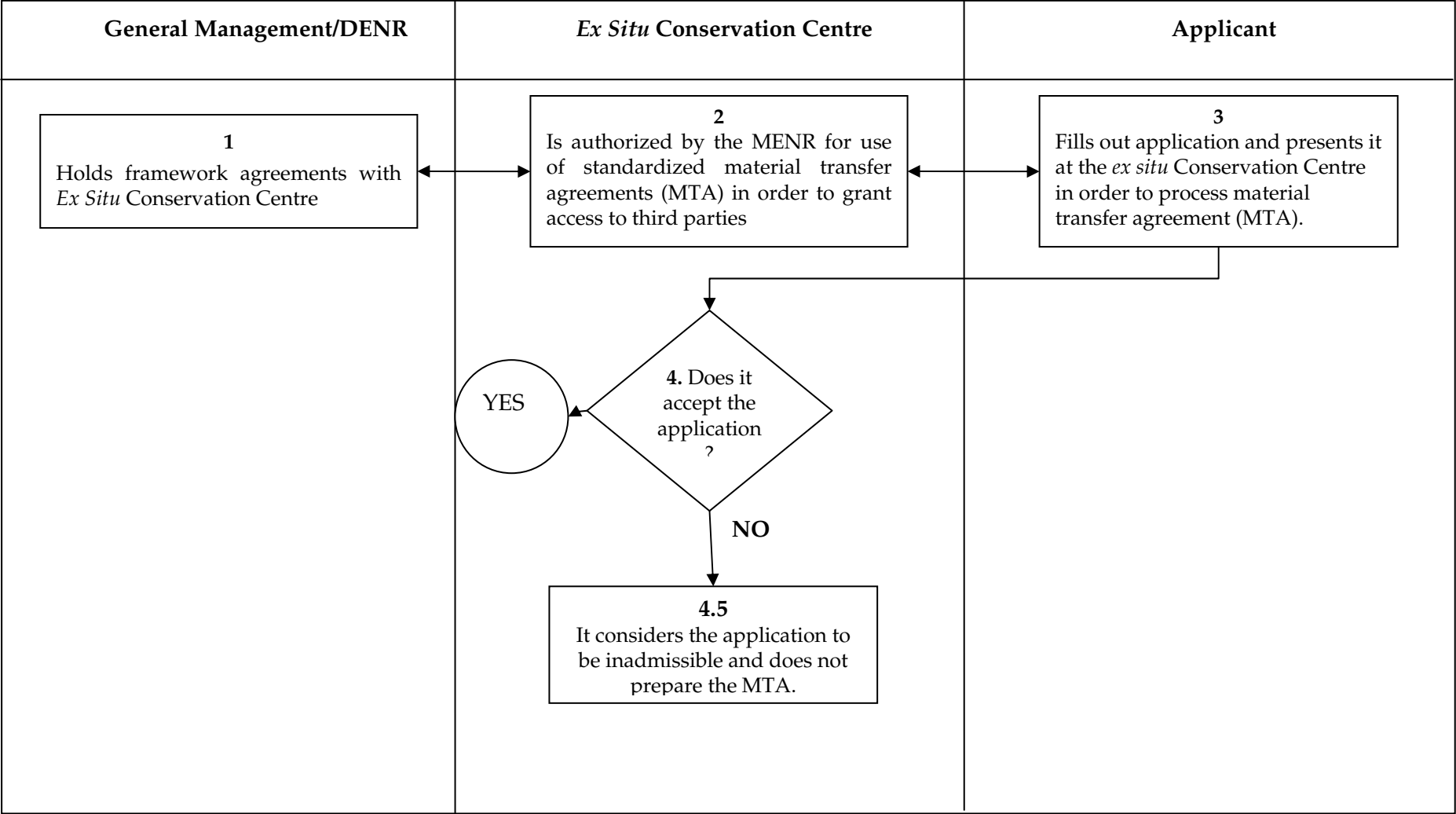


Figure 3.3 Technical administrative procedures on access to biochemical and genetic resources in *ex situ* conditions.



General Directorate/MENR

Ex Situ Conservation Centre

Applicant

YES

5

Approves the application, prepares the material transfer agreement according to the model approved by the MENR, and provides the genetic resource following the lineaments authorised by the MENR

It decides whether or not the new conditions are to be approved

6

Should new conditions exist that are not set out in the Agreement or in the previously approved MTA the Centre should inform the MENR of such conditions in order for them to be duly evaluated

It receives notification from the Centre regarding the MTAs signed

7

The MENR is to be notified of the signed transfer agreements within a period of X days from the date on which they were signed

8

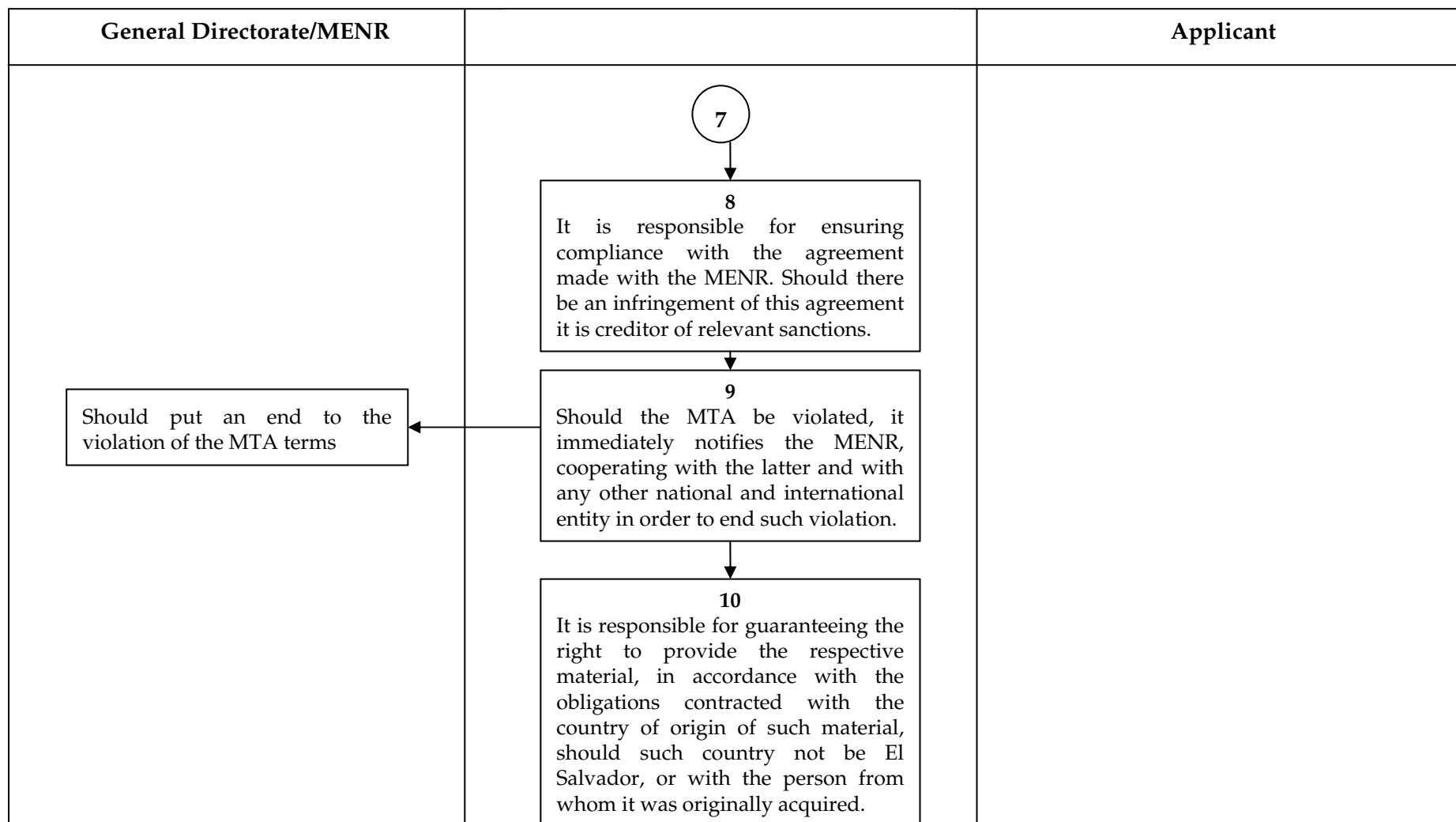


Figure 3.4A Ministry of Environment and Natural Resources stages of procedure for prospecting for access to the biochemical and genetic resources for industrial purposes

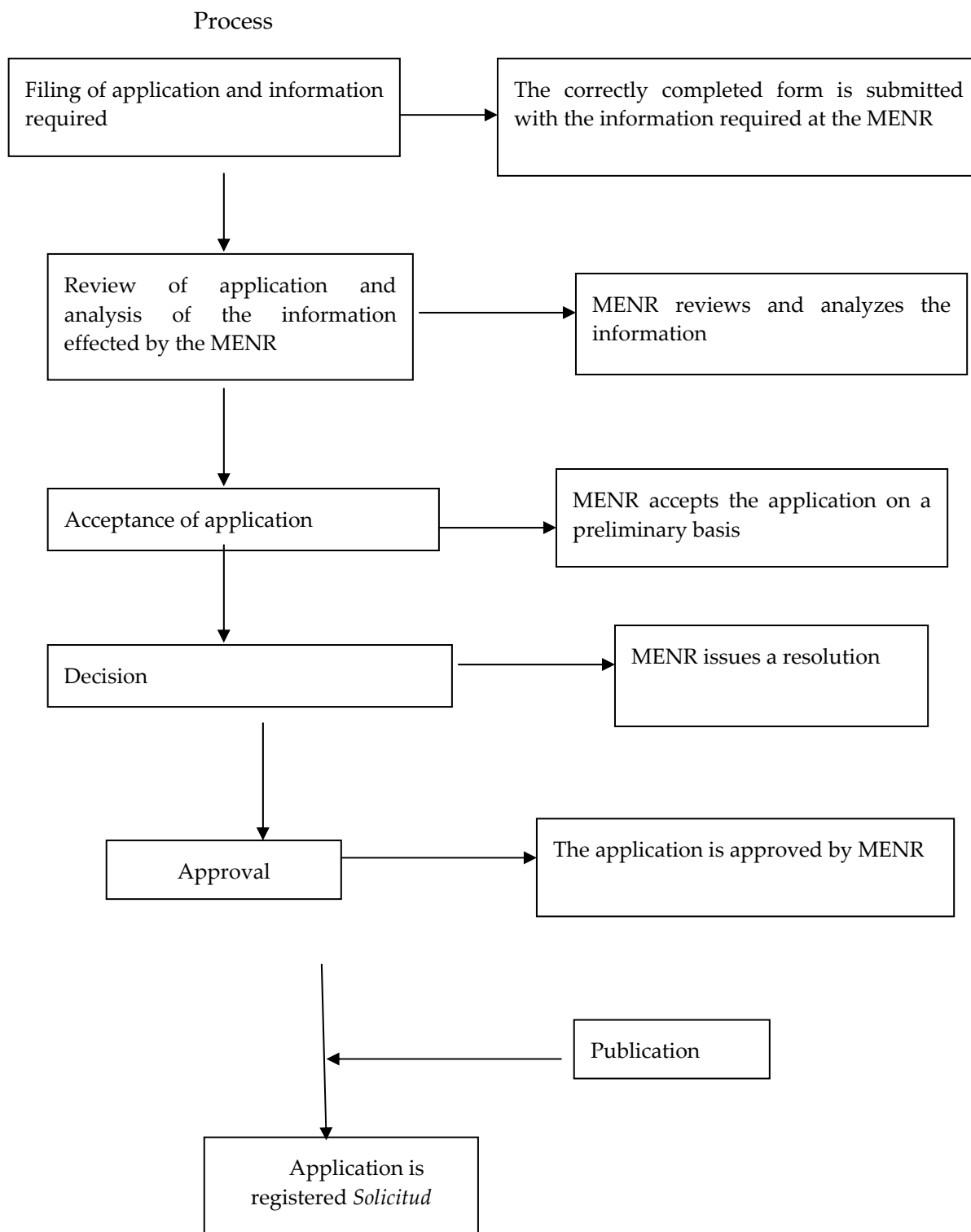
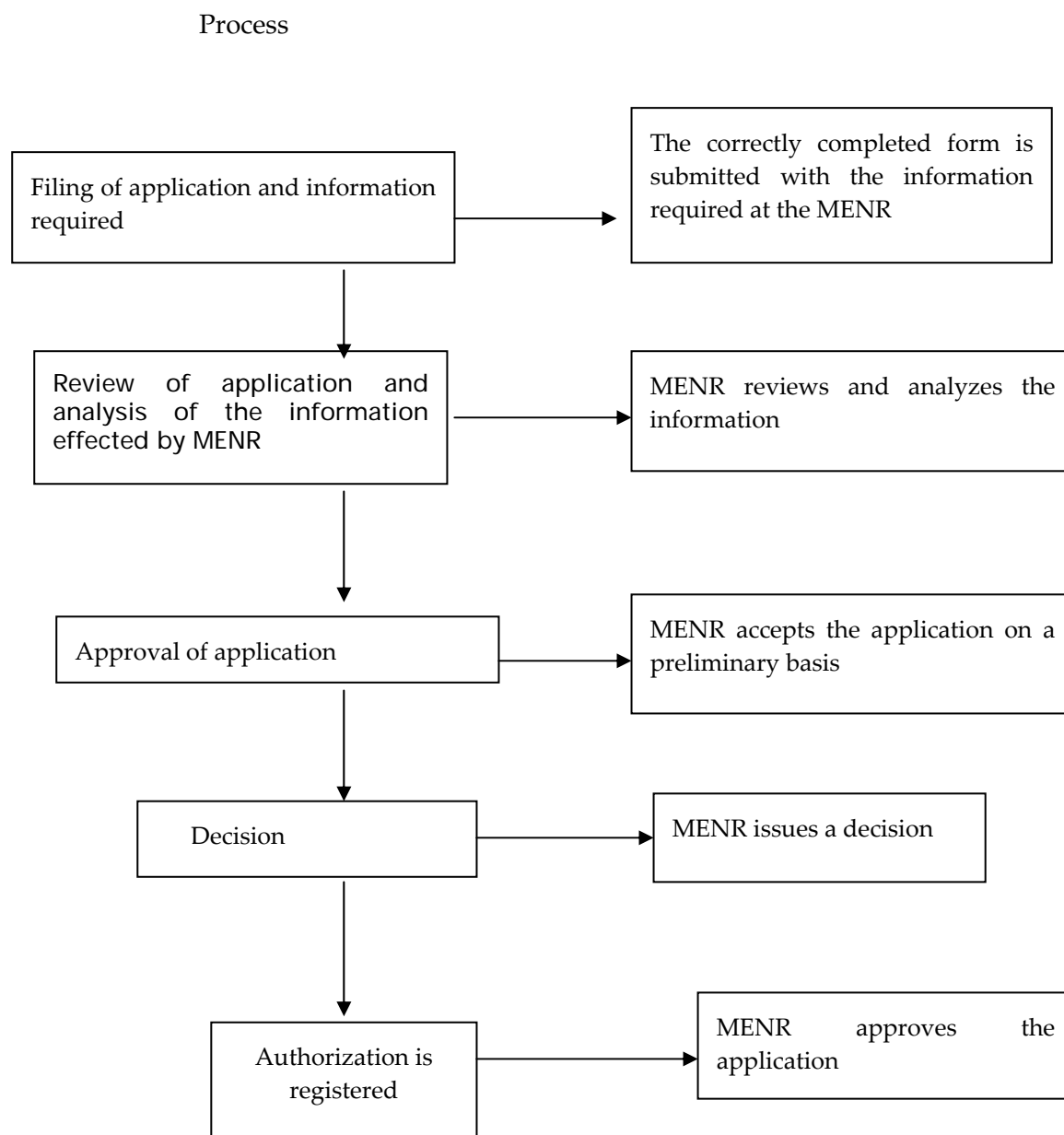


Figure 3.4B Ministry of Environment and Natural Resources stages of procedure for prospecting for access to the biochemical and genetic resources for academic purposes



Practical experiences and draft regulations on access before and after the General Environmental Law

Most of bioprospecting research has been carried out by universities, such as the University of El Salvador and the private universities, including Alberto Masferrer Salvadoran University (CONADIBIOS, 1998). They have collaborated with La Laguna Botanical Garden Association, Health Ministry, and foreign scientific or academic institutions (CONADIBIOS, 1998). The Health Ministry's Technical Unit of Medicines also conducted a study, considered as one of the most complete of its kind, which identified and separated an active substance of red carbon with healing capacity.

There are numerous cases of explorations carried out by companies that obtain natural raw materials for medicinal, agricultural and industrial uses. Consumer items such as essential oils, cosmetics, colorants, fatty oils and fibre, are produced. According to the report *El Salvador: current state of the exploration of the biodiversity*, one of the most noteworthy cases is the company ProBioTec. It is investigating secondary metabolites in some species of Salvadoran flora and collaborates with two German companies devoted to the study and exploitation of biodiversity, Analyticon AG and BioSys GmbH.

Cases have been known of publications and investigations conducted concerning El Salvador's genetic resources that did not require any type of permission or obtained a mere permit for collection or research. No information is available on these (Rafael Vega, pers. comm.). For lands outside protected wildlife areas or for materials in *ex situ* collections, the information is even more scarce.

The draft regulation has been used in practice to regulate access. There have been petitions from academic members to conduct certain research activities, particularly from the Pharmacy and Chemical Faculty of the University of El Salvador. In this sense, the researcher who was requesting the access desisted from the application in view of the requirements (Rafael Vega, pers. comm.).

Access to and exchange of materials has indeed existed in the past. As indicated earlier, the main protagonists have been the universities, certain companies from the private sector, and La Laguna Botanical Garden. The last-named has been carrying out bioprospecting activities with other organizations, such as universities and companies from the private sector.

With respect to cooperative agreements, contracts and regional agreements that affect the access to and exploitation of benefits, the following are worth noting.

- **Central American Protocol for Access to Biochemical and Genetic Resources and the Associated TK.** Its objective is to regulate access to biochemical and genetic resources, and the associated practices, innovations and knowledge that exist in any of the state members of CCAD. This document, which was approved by the Board of Ministers, aims to provide the framework for policies and strategies to unify the laws and mechanisms in Central American countries.
- **Convention for the Conservation of Biodiversity and Protection of the Priority Wildlife Areas of Central America.** This convention establishes the commitment offered by the state members of the CCAD to conserve the marine coastal land and biological diversity in the Central American region for the benefit of the present and future generations. Under Article 7, it refers to the need to recognize and rescue the knowledge, practices and technological innovations developed by native peoples in the region, that contribute to the use and conservation of biological resources.

Article 8 declares that the access to genetic material, substances, and products derived therefrom, related technology and the conservation thereof will be left open, under the

jurisdiction and control of the states in accordance with the mutual agreements established with reputed organizations.

In general, in Central America there are several regional networks for agricultural cooperation that influence access to and transfer of materials for investigation among them. There are cooperative networks for kidney beans (Profijol), maize (Promaíz) and coffee (Promecafé). All involve the participation of national investigation entities and international cooperation, and exchange materials and results of investigations.

Legal and other challenges in the functioning of the regulations relating to access

- The greatest difficulties to be overcome for the system on access are institutional.
- Jurisdictions defined in the different laws overlap and are duplicated, and this complicates access authorization procedures. Consequently, MENR has developed its access procedures for wildlife only.
- The information on access from the different institutions is obscure and scarce. This is evident in the technical and administrative elements in the legal advisory units of the institutions. Access contracts offer insufficient information and need to be more detailed.
- Human resource capacity is inadequate.
- The benefits or advantages from good negotiations are absent.
- The Ministry of Economy supports small and medium-sized companies that extract active substances from the flora resource. The German commercial firms do not appeal to the MENR for the corresponding authorization application or registration. This demonstrates an absence of institutional coordination and evaluation of the national efforts to define access policies and procedures.
- There is lack of dissemination of information and strengthening of institutional capacities to confront a relatively unknown and legally complex matter.

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4. Ghana

Kent Nnadozie

Introduction

Ghana was among the earliest countries to ratify the Convention on Biological Diversity (CBD), but has yet to put in place legislative, administrative and policy measures for its implementation. This is most evident with regard to issues related to access and benefit-sharing (ABS). There are efforts to implement the CBD, albeit limited in scope and largely at the institutional level. No specific laws or legal instruments have as yet been passed to implement the CBD, but the existing laws could serve the objectives of the convention, especially with respect to ABS. The mandate and activities of several institutions and ministries are relevant to the objectives of the CBD.

Legal status of genetic resources

Definition

Practically all the existing relevant legislation was passed before the CBD was even negotiated. As a result, many of the conceptual issues in the CBD are not addressed in these laws. Significant among these issues are the concepts of sustainable use, ABS, as well as the definition of and distinction between biological and genetic resources. They are used interchangeably, often focusing more on the physical biological materials than their genetic components. Hence, there is no official definition of the term “genetic resources”.

Ownership

The ownership of genetic resources is not specifically established in any law. However, some guidance could be found through logical extension or inference from the provisions of existing laws and practice.

The current Constitution of Ghana, adopted in 1992, does not contain express provisions with regard to the ownership or governance of biological or genetic resources (for details see The Ghanaian Constitution Web site at <http://www.ghanareview.com/Gconst.html>). Some of its provisions, however, relate to the subject or could provide some guidance. Most of these provisions are contained in Chapter 6 of the Constitution, which pertain to the Directive Principles of State Policy, and largely unenforceable. Article 37(9) of the Constitution enjoins the state to take appropriate measures to protect and safeguard the natural environment for posterity; and to cooperate with other states and bodies to protect the wider international environment for mankind (Sarpong 1993–95).¹⁴

The legal system of Ghana is based on the Anglo-American common law model. All rights are enforced through this pluralistic system, including rights to property. In Chapter 3, Section 11, relating to the laws of Ghana, the Constitution provides that:

1. The laws of Ghana shall comprise:
 - a) this Constitution;
 - b) enactment made by or under the authority of the parliament established by this Constitution;
 - c) any orders, rules and regulations made by any person or authority under a power conferred by this constitutions;

¹⁴ Environmental Justice in Ghana, RGL forthcoming. See also Review of Ghanaian Law Relating to Access to Justice on Urban Environmental Issues.

- d) the existing law; and
 - e) the common law.
2. The common law of Ghana shall comprise the rules of law generally known as the common law, the rules generally known as the doctrines of equity and the rules of customary law, including those determined by the Superior Court of Judicature.
 3. For the purposes of this article, "customary law" means the rules of law, which by custom are applicable to particular communities in Ghana.
 4. The existing law shall, except as otherwise provided in clause (1) of this article, comprise the written and unwritten laws of Ghana as they existed immediately before the coming into force of this Constitution, and any Act, Decree, Law or statutory instrument issued or made before that date, which is to come into force on or after that date.
 5. Subject to the provisions of this Constitution, the existing law shall not be affected by the coming into force of this Constitution.
 6. The existing law shall be construed with any modifications, adaptations, qualifications and exceptions necessary to bring it into conformity with the provisions of this Constitution, or otherwise to give effect to, or enable effect to be given to any changes effected by this Constitution

Guidance can only be sought by looking at the common law. Under common law principles, for instance, there is generally a close link between land and resources such that anything found on, under or above it is considered to be part of the land. In other words, the ownership of the land, *prima facie*, determines the ownership of the resources found on it. However, this general principle has, in many cases, been limited by the constitution or statutory law. Article 256 (6) of the Constitution of Ghana specifically vests ownership of minerals in the President of the Republic on behalf of the peoples of Ghana.¹⁵ This applies to resources found in both private and public lands. Common law would, expectedly, apply where either the constitution or statutory law has no specific provision: in this case, genetic resources.

In Ghana, genetic resources are considered as part of rights inherent in the ownership of land and no permits are required to access, exchange or export genetic resources. The constitution also recognizes customary law as being applicable in certain circumstances. However, customary law varies in different localities making the issue even more complex. Customary land tenure or principles of ownership also vary in different communities. The minerals, forests and wildlife are specifically provided for in statutory law. There is presumption that ownership of resources found on the land will be governed by the customary laws applicable to the land.

Genetic resources on privately owned land may be relatively straightforward, but that on land held under customary tenure – *skin* or *tool* land – is more complicated. The common principle in all of them is the collective ownership of such land. The constitution recognizes this in the provisions and prohibits the grant of freehold status to *stool* or *skin* lands.¹⁶

In the absence of specific legislation, the most rational basis for determining ownership of genetic resources in Ghana is probably according to the land tenure system applicable to the

¹⁵ "Every mineral in its natural state in, under or upon any land in Ghana, rivers, streams, water courses throughout Ghana, the exclusive economic zone and any area covered by the territorial sea or continental shelf is the property of the Republic of Ghana and shall be vested in the President on behalf of, and in trust for the people of Ghana."

¹⁶ Article 267 (1) "All stool lands in Ghana shall vest in the appropriate stool on behalf of, and in trust for the subjects of the stool in accordance with customary law and usage" (5) "...no interest in, or right over, any stool land in Ghana shall be created which vests in any person or body of persons a freehold interest howsoever described."

land where a given resource is found. Control over them is in practice more significant in the context of ABS and the provisions of the CBD. There is specific authority under the constitution for the parliament to make laws in respect of “natural resources”, no matter how defined.¹⁷

Article 268 (1) provides that

“Any transaction, contract or undertaking involving the grant of a right or concession by or on behalf of any person including the Government of Ghana, to any other person or body of persons howsoever described, for the exploitation of any mineral, water or other natural resource of Ghana made or entered into after the coming into force of this Constitution shall be subject to ratification by Parliament.”

An interesting aspect of the part of the constitution dealing with natural resources is that a wide interpretation of the term “natural resources” would mean that, since no particular law has as yet been made in respect of genetic resources, all access contracts must be ratified by the parliament. Such a wide interpretation of the term might seem arguable because in Article 269, which obliges the parliament to set up different commissions under this part of the constitution, within six months of coming into force, stipulates both Forestry and Fisheries Commissions. There is a clear implication that “natural resources” includes biological resources, as indicated by the forest and marine resources.

Article 268 (2) empowers parliament to exempt any particular class of transactions, contracts or undertakings relating to any category of natural resources from this requirement, i.e. parliamentary ratification. What is not clear is whether access contracts should be ratified by the parliament for the permit or consent required for ABS. This would appear to be the practical implication of its provisions in this regard.

Policy framework

There is currently no clear or specific policy on ABS in the country. There are many statements that are dispersed in several policy documents that have relevance and indirect bearing on ABS. They are however, neither explicit nor comprehensive enough, hence the need for a definite policy on ABS (Enu-Kwesi, 1997). Existing policies in Ghana bearing on ABS include:

- Ghana’s Environmental Policy outlines the National Environmental Action Plan, which was published in 1991. It ensures sound management of resources and the environment to avoid overexploitation. Its main principles include:
- optimum sustainable yields in the use of resources and ecosystems;
- use of incentives in addition to regulatory measures,
- public participation in environmental decision-making; and
- international cooperation.
- Under the policy the government is committed to:
- developing and maintaining a professional cadre within the country to supervise, coordinate, implement and enforce procedures and legislation. This is essential for safeguarding the environment and maintaining sound ecological systems; and
- establishing an adequate legislative and institutional framework for monitoring, coordinating and enforcing environmental matters.

¹⁷ Article 269 (1) “Subject to the provisions of this Constitution, Parliament shall, by or under an Act of Parliament, provide for the establishment, ...[of] such other Commissions as Parliament may determine, which shall be responsible for the regulation and management of the utilization of the natural resources concerned and the co-ordination of the policies in relation to them.”

- These commitments are still far from accomplished.
- The Forest and Wildlife Policy in Ghana was adopted in 1948, but became inadequate in dealing with emerging technical, legal and policy issues, including international developments. Moreover, it emphasized the maximum exploitation of the country's forest resources without provision for conservation or use. Consequently, a new one was developed in 1994 taking these current issues into account. The guiding principles of the New Forest Policy include:
 - the need to incorporate traditional methods of resource management into national strategies, where appropriate;
 - the retention of a share of financial benefits from resource use to fund the maintenance of resource production capacity and for the benefit of local communities;
 - incentives of forest and wildlife fees and taxes to encourage more rational and less wasteful use; and
 - the need to develop a decentralized system by involving local people in matters of their welfare.

Relevant institutions

The 1992 Constitution makes provisions to establish certain bodies on biodiversity. The Forestry Commission was established under Forestry Commission Act, 1993 (Act 453). It is charged with the responsibility to regulate and manage the use of, and coordinate policies on, forest and wildlife resources.

The Fisheries Commission coordinates policies on fisheries and other marine biological resources, and has responsibility for their regulation, management and use.¹⁸

The Environmental Protection Council was established in 1973 to focus on issues of environmental management. In 1992, the Environmental Protection Council was converted into the Environmental Protection Agency (through Act 490). It has the power to enforce standards, including regulations and guidelines with regard to the environment generally (Enu-Kwesi, 1998).

The Ministry of Environment was set up in 1993, but was subsequently integrated with the Ministry of Science and Technology to become The Ministry of Environment, Science and Technology (MEST). Now as the Ministry of Environment and Science (MES), it has the mandate for biodiversity management. In 2002, a National Biodiversity Strategy for Ghana was instituted and a National Biodiversity Committee comprising a wide range of ministries and departments related to biodiversity was instituted. Subsequently, a Biodiversity Unit was established within MES to coordinate the country's programmes related to biodiversity and the implementation of CBD. However, it lacks legal 'clout' or mandate and the appropriate resources and capacity to function effectively through appropriate legislation or regulation.

The other ministries or departments of the state with direct relevance in biodiversity-related issues are the:

- Ministry of Lands and Forestry (MLF)
- Ministry of Food and Agriculture
- Ministry of Health
- Ministry of Trade

¹⁸ See 1992 Constitution Arts 258, 269; Forestry Commission Act, 1993 (Act 453); Fisheries Commission Act, 1993 (Act 457).

- Ministry of Tourism
- Ministry of Local Government and Rural Development (MLGRD)
- Department of Wildlife
- Customs, Excise and Preventive Service
- Water Resources Commission

The Plant Genetic Resources Centre (PGRC) at Bunso is under the Council for Scientific and Industrial Research (CSIR). PGRC collects studies and maintains plant genetic resources by *in situ* methods in farmers' fields and elsewhere, and *ex situ* methods through gene banks. The centre also characterizes, evaluates, conserves, distributes and documents plant genetic resources. The resources conserved or developed under its mandate are sometimes distributed to local researchers in various institutions in the country and foreign researchers for their research projects, as well as to local farmers who request them. There are, however, no comprehensive records of the distribution of germplasm, subsequent uses or destination of the resources since its inception.

The following are the most relevant research institutions and establishments under CSIR, carrying out research on specific crops and disseminating the findings and germplasm to farmers:

- Savannah Agricultural Research Institute (SARI), Tamale.
- Forestry Research Institute of Ghana (FORIG), Kumasi, maintains arboreta of forestry species, a seed storage facility for forest seed germplasm, and a butterfly sanctuary.
- Crops Research Institute (CRI), Kumasi, maintains a working collection of cereal, vegetable and legume seeds, and a field gene bank of root and tuber crops, plantain, mango and citrus.
- Oil Palm Research Institute (OPRI), Kade, conducts research in oil palm and coconut, and collects and conserves germplasm in the field.
- Agricultural Research Station (ARS) of the University of Ghana, Kade, maintains germplasm of plantation crops, including citrus, mango, cola, oil palm, avocado, plantain, cassava and cocoyam.
- Botany Department of the University of Ghana has a botanic garden, a herbarium and *in vitro* facilities for conserving and multiplying root and tuber crops, like yam, cocoyam, plantain and pineapple.
- Biotechnology and Nuclear Agriculture Research Institute (BNARI), Kwabenya, is an institute under the Ghana Atomic Energy Commission (GAEC) and conserves and multiplies yam, cassava, pineapple and plantain germplasm *in vitro*.
- Animal Research Institute (ARI), Accra, maintains a collection of local and introduced pasture, legumes and grass germplasm.
- Cocoa Research Institute of Ghana (CRIG), New Tafo, maintains field gene banks of cocoa, coffee, cola, shea butter and cashew across the country.
- Ghana Wildlife Department administers an estate of 18 terrestrial sites and 5 coastal wetlands (Ramsar sites) as protected areas. The terrestrial sites include 7 National Parks, 6 Resource Reserves, 1 Strict Nature Reserve and 4 Wildlife Sanctuaries.
- Science and Technology Policy Research Institute (STEPRI) undertakes policy research and advises other institutes on policy and legislative issues pertaining to science and technology, including IPRs.

PGRC is the primary agency, with a mandate to collect, maintain and conserve crop germplasm. However, a number of departments in the universities in the country, for instance the Crop Science and Botany Departments at the University of Ghana, Legon, maintain modest collections, including as tissue culture.

All these institutions and bodies address different aspects of biodiversity, but none is charged with statutory responsibility to formulate, coordinate and execute programmes and policies on biodiversity. According to the National Biodiversity Strategy for Ghana,

“in spite of the existence of a number of institutions and departments, biodiversity management and conservation has been far from satisfactory. A major constraint has been the lack of coordination, collaboration and networking between and among policy developing institutions on the one side and policy-implementing institutions on the other side. The consequences have been overlaps, duplications, conflicts, unhealthy competitions and disharmony. Furthermore, there are undeniable weaknesses in the capacities and capabilities of some institutions.”

International legal obligations

Ghana has signed and ratified the two key international agreements directly related to ABS in genetic resources, namely CBD and ITPGRFA. It is also a party to several of the major conventions of relevance to biodiversity including:

- Convention on the Conservation of Migratory Species of Wild Animals (CMS or Bonn Convention);
- African Convention on Conservation of Nature and Natural Resources;
- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);
- Convention on Wetlands of International Importance Especially as Water Fowl Habitat (Ramsar);
- International Plant Protection Convention (IPPC);
- International Tropical Timber Agreement (ITTA);
- United Nations Convention to Combat Desertification in those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (UNCCD);
- Convention Concerning the Protection of the World Cultural and Natural Heritage (The World Heritage Convention);
- African Regional Seas Conventions: Convention for Cooperation in the Protection and Development of the Marine and Coastal Environment of the West and Central African Region.

Ghana is also a member of WTO and therefore subscribes to its numerous agreements including the TRIPS Agreement. Many of these instruments are largely framework treaties, which provide general guidelines or measures, but leave the implementation to the parties through national legislative or policy instruments or mechanisms. Ghana has ratified these treaties, but efforts to implement them at the domestic level through the enactment of appropriate legislation as well as the provision of the necessary policy, institutional and administrative measures is limited.

Access and benefit-sharing provisions

Ghana's approach to addressing biodiversity issues is largely sectoral, resulting in a fragmented governance to biological resources. It further impedes efforts to achieve a more coherent approach to addressing the relevant issues and presents a confusing policy environment for outsiders seeking access to the country's genetic resources. This situation is exacerbated by limited financial and human resources, poor coordination as well as overlapping mandates and jurisdiction between agencies and the government. There is the need to establish a body that will formulate, coordinate and execute programmes and policies on biodiversity.

There are no established rules or procedures on access to genetic resources in Ghana or specific institutions or departments mandated to process applications or grant permission for

access. Many institutions and interested parties adopt ad hoc procedures or none at all to obtain or export genetic resources. Appropriate institutions could be identified from those currently in existence to issue permits for access in their specific areas of mandate and to lay down benefit-sharing conditions or mechanisms. This could be achieved by establishing guidelines when developing the appropriate legislative and administrative framework. The Crop Research Institute (CRI), Ministry of Food and Agriculture (PPRS Department), Forestry Department, Ghana Wildlife Department, PGRC and EPA are potential competent authorities for this purpose.

Intellectual property rights

IPRs rank high in the non-biodiversity issues and most controversial aspects of ABS that affect genetic resources. The CBD itself as well as the ITPGRFA recognize that IPRs are relevant and could affect their implementation in significant ways. As a result, no discussion of ABS regimes in any context is complete without consideration of IPRs.

The Government of Ghana passed Law 332 on Patents in 1992 and the Patents Regulations (1996) L.I. 1616 to make the law operative. It repealed the Patent Registration Ordinance, which required that patents be first obtained in the UK and then registered in Ghana.

Under Section 1(2) of the Patents Law, “an invention may be, or relate to a product or a process”. Section 1(3) states that

“the following shall not be regarded as inventions:

- (a) discoveries, scientific and mathematical theories; or
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than microbiological processes and the products of such process”.

Section 64(1) provides for the grant of a “Utility Model Certificate” or “Petty Patent”. It is granted to inventions that are new and industrially applicable, but they do not need to satisfy the test of inventive step or non-obviousness.

There are currently no laws explicitly recognizing or protecting the TK of local communities, especially as they relate to genetic resources. Hence, there is no legal footing to enable the enforcement of any rights over TK associated with genetic resources for any local community or group. Current intellectual property laws, whether patents or trademarks, also do not recognize or protect TK. Traditional and intellectual rights of local communities extend well beyond what is recognized and protected under the current prevailing systems, because they incorporate a wide range of subject matter.

Other relevant laws

The Government of Ghana enacted a law, Act 307 of 1965, to regulate the import and export of plant materials. This law established the Plant Protection and Regulatory Services Department (PPRSD) within the Ministry of Food and Agriculture, which enforces quarantine regulations in the country. It is required that import permits must be obtained for importation of *in vitro* cultures of any crop and imports must be accompanied by relevant phytosanitary certificates and export permits from the country of origin. Certain materials, like soil or plants with soil, plants or plant products infested with pests and diseases and specified plants are prohibited. The implementation of the plant quarantine laws has not been very effective, because of lack of adequate capacity, facilities and resources required for effective discharge of the duties stipulated under the Act. This Act requires the granting of permit to import or export germplasm, but its purpose is entirely different from ABS issues. However, this does not preclude the adaptation of its mechanisms to meet some of the requirements of ABS.

The Wild Animals Preservation Act, 1961 (Act 43) provides for the establishment of reserves, national parks and sanctuaries. It contains a list of protected species and regulates hunting and trading in trophies. Pursuant to the law, subsidiary legislation such as the Wildlife Conservation and Wildlife Reserve Regulations have been passed.¹⁹ The regulations ban the hunting, capturing or destruction of such endangered species as chimpanzees, lions, elephants, crocodiles, parrots and turtles in consonance with CITES, and others could only be hunted with a licence from the wildlife department.

Collaborative initiatives and existing ABS contracts

Ghana collaborates with scientists and institutions in Africa, Europe and North America that are involved in the exchange of materials and germplasm. Generally, no permits are obtained either for collection of such materials or germplasm or for their export. At best, the main clearance usually sought and obtained is from the plant quarantine authority. Similarly, no “benefit-sharing” mechanism exists and only a few contractual agreements, albeit mostly general in nature, are signed between local scientists (and institutions) and their foreign or external collaborators (or their institutions).

Initial indications suggest that few or no records are available for much of the bioprospecting activities going on in the country including requests for, exchanges or export of genetic resources. This is the case even for the most recent post-CBD activities. There are no standardized processes, reporting requirements or centralized authority to supervise these activities. Hence, where available, records are scattered among the various institutions involved in the relevant activities. Some of the institutions that have some form of records do not maintain them in any consistent, coherent or structured manner. In some cases, different individuals or officials within the same institution have different bits of the relevant information on specific transactions or activities.

The search for active ingredients from biological materials within the country is carried on by both private and public establishments. Indications are that there are private laboratories engaged in the research and development of natural products and actively searching for active ingredients and components from extracts of roots, bark, leaves, flowers and seed in many plant species, often relying on ethnobotanical knowledge and information. There are also specific public institutions engaged in similar activities. Since 1995, FORIG has been investigating extracts from the barks of mangrove species as well as extracts of ‘prekese’ seeds. Also, the Centre for Scientific Research into Plant Medicine (CSRPM) has been searching for active ingredients in a number of plant species, including *Cryptolepis sanguine*.

More recent, and in fact ongoing, activities include the collaboration agreements for biodiversity access and research between Diversa Corporation in USA and the University of Ghana, which grants Diversa access to biodiversity through a collection and collaboration network. This agreement is specifically with the Department of Biochemistry at the University of Ghana and gives Diversa the rights to discover genes and commercialize products from small environmental samples supplied by the former. In exchange, Diversa will provide scientific training, annual research support, and royalties on Diversa’s revenues from products developed under the agreements. The specific details of the agreement are not publicly available nor are the quantity of samples that have so far been shipped to Diversa

¹⁹ LIs 685 and 710 as amended by LIs 1283 and 1284.

under the agreement.²⁰ It was stated by one of the officials involved that consents were obtained from the government (Ministry of Environment) before the agreement was concluded even in light of the lack of statutory or regulatory stipulations for it. However, the nature and terms of the consent could not be ascertained.

Many of the institutions involved in bioprospecting have collaborative arrangements that are either local or international, or both. The PGRC collaborates with institutions and individuals within the country, in West Africa and in developed countries, as well as international organizations such as the Consultative Group on International Agricultural Research (CGIAR) centres, especially the International Plant Genetic Resources Institute (IPGRI). CSRPM collaborates with Health Search in the USA and has sent 15 plant species under their agreement. A private laboratory was found to have collaborative arrangements with Shaman Pharmaceuticals in USA by supplying samples for screening to develop commercial products.

The CSRPM obtained permission to collect materials from different sources. However, the authority, and the nature and conditions of the permission were not identified. Also, permits were obtained at the airports before the materials were exported at no cost. The quantity of biological materials sent to Shaman Pharmaceuticals for investigation is estimated at about 5 kg at an unspecified period (post-CBD, nevertheless). In this case, the compensation obtained was said to be about two hundred United States dollars. Since there was no legal requirement, there was neither compensation nor permission from the local communities where the materials were collected.

Many academic institutions and departments in the universities as well as individual academics or researchers have been involved in the exchange of materials with or transfer to other academic institutions or researchers in several countries. These are mainly for academic purposes, but sometimes for industrial or commercial activities with private or public sector establishments. These exchanges are largely free. Specific examples include the Botany Department, University of Ghana, with Missouri Botanical Gardens (MBG) and the university with the National Cancer Institute (NCI), USA. It is estimated that a total of about 5000 plant species²¹ were sent out under these collaborative arrangements lasting about 4 years, with between 50 and 120 plant specimens sent out in each shipment.

In many of these transactions, there was generally no follow-up once the materials were sent out, nor were there any reporting on the fate of the materials or who the subsequent transferees have been. Only in a few cases, for instance the private laboratory, were there expectations of and actual feedback on the materials sent. Since Shaman Pharmaceuticals was most likely involved in this case, its contracts have the standard provision to report on progress of the materials received to their numerous collaborators globally. Also, in the case of CSRPM, the feedback was not expected on the outcome of screening and research done, as well as active compounds found in the materials and their potential for human use. Hence, there is no indication that any feedback was received under the agreement.

Prior to the CBD, there were a number of permit systems relating to the exploitation of different types of biological resources. The permit for timber concessions and tree-felling or logging and the royalty or stumping fee, and the hunting permit from the Department of

²⁰ According to the statement released by Diversa, "By accessing biodiversity globally, Diversa is able to combine discovery of novel genes with laboratory evolution technologies to develop products with characteristics superior to those of products identified using traditional culturing methods or through accessing public databases," stated Dr Jay M. Short, President and Chief Executive Officer of Diversa. "Diversa is targeting high-value product opportunities such as orally active drugs, including new antibiotics and antifungals, as well as novel biocatalysts, all of which can be discovered and developed from small environmental samples using our patented technologies."

²¹ 2000 on record, but about 5000 based on private communication with one of the scientists involved.

Game and Wildlife are examples. However, in the context of the CBD and with respect to genetic resources generally, permits are largely not sought before collections are undertaken or materials exported, since there are no specific obligations to do so. The only permit mostly sought was from the Plant Quarantine Unit at the airport, to export and usually at no cost. It appeared to be irregular and almost discretionary, but not standard practice. Permission is also usually sought from the Forestry Department to collect from designated forest areas, as did the University of Ghana under the MBG and NCI agreements.

Contractual arrangements

With regard to the supply of materials within the country or for purely academic purposes, there is usually no contract or agreement covering materials to be transferred. However, there generally appears to be contractual agreements where external collaborators or institutions are concerned. The number and contents – terms and conditions – of such contracts are not easily available. However, two particular agreements were found: one between the Botany Department, University of Ghana and the Missouri Botanical Garden on 14 February 1993; and the other between the University of Ghana and the Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute (NCI), USA, on 14 May 1993. Both agreements are essentially operated through the Botany Department and the Missouri Botanical Garden. The plant samples are collected for screening for bioactivity against various human cancers, HIV/AIDS and other diseases, by the NCI.

The agreements contain some basic provisions about benefit-sharing, reached without the involvement of any national authority, ostensibly because none was designated as a National Focal Point (NFP) with the relevant mandate. They also did not involve local communities. Provisions relating to capacity building, facility improvement, and technical and professional development were not obligatory and lack the means or parameters to enforce them. They are located in sections on objectives rather than in the operative parts of the agreement.

Main legal issues related to ABS and conclusion

The definitional and IPRs global legal issues related to ABS have yet to be directly experienced in Ghana. This is mostly because there is lack of legislation on ABS issues, which have not yet been tested or confronted nationally. However, one of the principal problems with the system is the absence of a statutory authority to deal with ABS issues. There is no regulatory mechanism to empower the biodiversity unit and the subsequent National Biodiversity Committee in MES. Hence, they coordinate capacity or convene the national process to develop appropriate regimes for the country.

The local communities are completely left out of the ABS, because they have neither the knowledge, capacity, nor the resources to protect their own interest. They do not have the legal foothold to anchor the enforcement or defence of their rights and interests even if they could. There is no specific law protecting their interests as far as genetic resources or associated TK goes, except perhaps through a generous interpretation of the constitution regarding land tenure and rights.

The non-legal challenges include:

- low level of awareness, even of the institutions engaged in the relevant activities of the legal international aspects of bioprospecting and genetic resources, poses a major challenge to ABS administration. These include the provisions of the CBD – requiring PIC, MAT for benefit-sharing; IPR aspects; issues of ownership and subsequent use or transfer of materials; and results of research;
- lack of trained staff and awareness, especially among coastal communities, of the interaction between various development actions and the environment, particularly biological resources;

- inadequate:
 - facilities for monitoring and enforcement of policies and legislation;
 - data on near-shore oceanographic processes; and
 - financial resources for activities in the marine and coastal environment.

The Biodiversity Unit of MES is tackling these issues at the policy level. There is recognition of the need to establish a competent national authority to formulate, coordinate and execute the programmes, policies and legislation on biodiversity, including ABS (Sarpong 2001). Most stakeholders expect this body to be highly placed, with sufficient political clout to carry out its mandate. The prevalent view appears to favour the establishing of a corporate National Biodiversity Commission. The structure and governance would be a national decision, but the membership would be drawn from a wide range of stakeholders and relevant ministries.

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5. Malawi

Symon Osman Mandala

Procedures and guidelines for access and collection of genetic resources in Malawi

These serve to ensure that the government is committed to promoting research in the proper management and use of biodiversity to benefit the country.

The objectives of the guidelines are to:

- ensure that:
- research on Malawi's genetic materials conserves biological diversity and that exchange of germplasm and commercialization of research results benefit Malawi economically;
- expatriate researchers or collectors work closely with competent local researchers to safeguard Malawi's interest;
- research projects on genetic resources and those involved in exchange of genetic resources and germplasm, encourage collaboration with foreign researchers to boost Malawi's socio-economic development and avoid fragmentation and duplication of research efforts;
- encourage:
- research projects to properly manage, conserve and use genetic resources; and
- the establishing of gene banks and genetic data banks (*in situ* and *ex situ*) to form strong linkages with other gene banks, including that of the Southern African Development Community (SADC).
- Users of the guidelines are:
- foreign scientists and research institutions that plan to conduct research involving the collection of genetic resources;
- local scientists and research institutions that plan to collect and export genetic resources for analysis or as part of an exchange programme with a foreign institution, and those funded externally on research projects involving the collection of Malawi's genetic resources; and
- Malawi Government Officials at ports of entry.

Research, material transfer and contractual agreements

These are tools used to define research collaborations between local research organizations and foreign research partners, and the rights and obligations of the parties in the collecting and using of the genetic resources. These include various categories of material transfer agreement.

- Academic collectors for research use only. This is an agreement that is issued by organizations for routine academic collections. No transfer to third parties is allowed under this agreement except for academic research purposes and with the original provider's written consent.
- Non-profit-making collectors. The agreement is issued to a non-profit institution collecting in scientific fields with possible commercial applications. Transfer to third parties is allowed, but the recipient is required to sign a contractual agreement with each third party to preserve the original provider's rights and in either case with the written consent of the original provider.
- Profit-making collectors. This agreement will be issued to the private sector collecting for possible commercial applications. Transfer to third parties is allowed with prior written consent of the original provider.
- Collection on customary land. This is an agreement that defines community resource rights to samples collected on customary lands and benefit-sharing requirements, and provides for a

written verification of PIC by the participating communities. The material provided is subject to customary rights.

- Use with the associated is intended to define the associated trade protection of TK collected from Malawian herbalists and traditional healers. It includes benefit-sharing requirements and provides a written verification of PIC.

Agricultural germplasm agreement for use with non-profit collectors

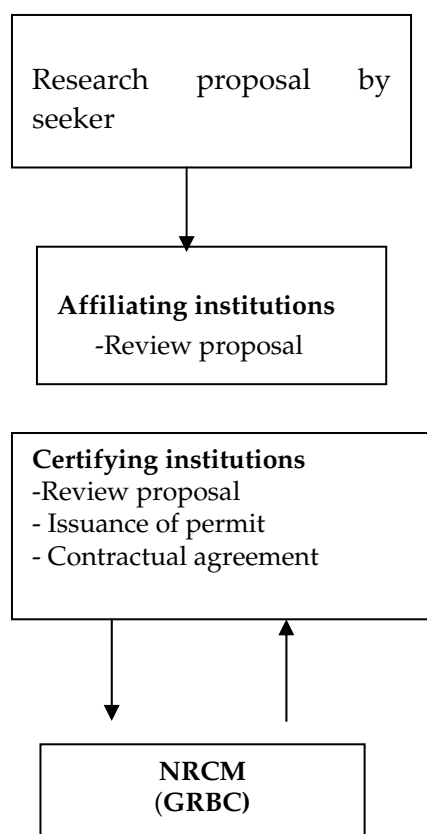
This agreement is intended for the collection of agricultural germplasm. It allows research use of the transferred germplasm and third party transfers to multilateral agricultural research organizations. The material transfer agreement for profit-making collectors shall be used for the third party transfer of agricultural germplasm to private companies.

Benefit-sharing formula

Malawi does not have a benefit-sharing formula. Collaborators depend solely on negotiations to arrive at MAT with researchers. These negotiations use the contractual and MTAs. These agreements are signed by the provider (government) and recipient (researcher) through the certification process by designated sectoral institutions. The absence of the benefit-sharing formula and total reliance on negotiations to arrive at MAT between the provider and researcher is viewed as a weakness. In addition, not all genetic resource users are covered, since the emphasis is on the transfer of genetic resources for research purposes.

The National Research Council of Malawi (NRCM) was established in 1974. It coordinates various scientific and technological activities through various technical committees. The Genetic Resources and Biotechnology Committee (GRBC) deals with all issues concerning genetic resources and biotechnology. Its members are drawn from the University of Malawi (Bunda and Chancellor Colleges), Malawi Police Service, Malawi Revenue Authority, Museums of Malawi, Ministry of Commerce and Industry, Ministry of Agriculture, Irrigation and Food Security, Biotechnology Ecology Research and Outreach Consortium (BiOEROC), Forestry Research Institute of Malawi, Malawi Plant Genetic Resources Centre, National Herbarium and Botanical Gardens of Malawi and Malawi Bureau of Standards.

Decision-making route for an access seeker:



6. Nigeria

Kent Nnadozie

Introduction

Nigeria is a federation comprising 36 states and the Federal Capital Territory, divided administratively into local government areas. This federal structure of the polity poses peculiar challenges in general political governance of the country, as well as in the ownership and control of genetic resources and, by extension, the range of issues concerning the governance of ABS. See Nnadozie (2003) for a more general discussion of access to genetic resources in Nigeria.

The determination of ownership and control is a function of national and subnational law, which means the laws of the federation and the component states in Nigeria. However, the extent of the powers of the component states to enact such laws remains uncertain, because of overlaps in jurisdiction. In the case of national parks or federal reserves, the legal issues of respect, access, and benefit-sharing are reasonably clear-cut. The governing law explicitly vests “ownership of every wild animal and plant ... and anything whatsoever, whether of biological, geomorphological or historical origin or otherwise, existing or found in a national park” in the federal government, subject to its control and management for the benefit of Nigeria and mankind generally.²²

The issue of ownership is quite critical in addressing these issues, but equally important is the question of control and right to regulate. This is where the dilemma of the Federal system of government raises the major challenges. The constitution is not explicit on the issue and the national legislature has yet to enact any general laws on the matter, but the existing laws already give significant authority to the states over natural resources within their respective territories (Nnadozie 2001). Guidance can, however, be sought from both the constitution and other laws including common law. Nigeria adopts the legal system that combines the constitution, statutory, common law and customary law as sources of law. Under this system, where there are no specific statutory provisions on any matter, the common law, or in some cases customary law, applies.

The predicament of the federal system becomes even more apparent when considered in the light of some specific provisions of 1999 constitution. IPRs – copyright, patents, trade marks, industrial designs, and merchandise marks – and certain aspects of trade (interstate and international) are under the exclusive jurisdiction of the federal authority. Land matters, forestry, and forest resources are within state competencies. Federal powers regarding forest resources and wildlife are limited to federal reserves and national parks.²³ Under the constitution, the federal government can only designate an area as a national park with the consent of the government of the state or states in whose territory it is to be established.²⁴ There is also concurrent jurisdiction on matters of the environment generally, though Federal laws will supersede state laws in case of any conflict. The various forestry laws of the states empower the state governments to constitute as forest reserves any land at the disposal of the government or any land the state deems that the forest growth on such lands should be protected or reserved, or forest growth be established.²⁵

²² Section 20(1).

²³ See National Park Services Decree, No. 46 of 1999.

²⁴ See Item 40 of the Exclusive Legislative List in the Second Schedule to the Constitution of the Federal Republic of Nigeria, 1999; see also Section 19(1)(c)(i) National Park Service Decree No. 46, 1999.

²⁵ See Forestry Law of Lagos State, Cap 51 Laws of Lagos State, 1972, Sec. 4(1).

Furthermore, under the Land Use Act of 1988, with the exception of already existing federal land and the federal capital territory, all land comprised in the territory of each state in the federation is vested in the governor of that state and such land shall be held in trust and administered for the use and common benefit of all Nigerians.²⁶ By virtue of the common law, what is on the land *prima facie* belongs to the land and is under the authority of the governor of the state.

Based on these laws and provisions, the jurisdiction to adopt legislation on and control access to the physical biological materials, including genetic resources, resides primarily with state governments. The protection of the associated knowledge and information through formal IPRs is clearly within the exclusive legislative competence of the federal government. This is not simple and straightforward in practice: for instance, the Federal Environmental Protection Agency Decree 1988, as amended, grants the Federal Environmental Protection Agency (FEPA) the mandate to regulate the environment generally, including the conservation and use of biological diversity. This creates a major overlap in jurisdiction and a potentially conflict situation, even though in light of the provisions of Article 15 of the Convention on Biological Diversity (CBD), that jurisdiction and mandate is understandable.²⁷ While reaffirming the sovereign rights of nation-states over genetic resources within their jurisdiction, article 15 does not necessarily confer on them a property right over these resources (Olawale 1995; 1997). However, countries with a federal system of government, such as Nigeria, face peculiar challenges regarding administrative competencies and jurisdiction for regulating the access to genetic resources and biological resources more broadly.

Definitions

There is no clear definition of genetic resources in any general law in the country just as the issue of ownership and control is still uncertain.. The only attempt is in the National Park Service Decree which adopts in verbatim the definitions in the CBD in respect of: “biological diversity”, “biological material”, “genetic material” and “genetic resources”. The CBD definitions of these terms are notoriously vague and unhelpful in practice.

The decree defines “prior informed consent” as “consent based on prior information on how and by whom the genetic resources or knowledge relating to the genetic resources would be subsequently used and the scientific and financial value of the genetic resources based on the most current and advanced state of knowledge and technology available worldwide.” This is probably one of the few laws which have attempted to define that concept.

Some guidance could also be sought from the forestry laws of the states, but given that they were enacted long before the CBD, no references are made to terms ‘genetic’ or ‘biological resources’ per se. There is also no definition related to the terms in their current conceptual interpretation, nor is the actual legal status of these resources stated. Notwithstanding that the primary focus in the enforcement and implementation of existing forestry laws has been primarily on timber products and, in some cases, wildlife, their scope could easily be extended to cover access to genetic resources, especially in view of the broad definition of “forest produce”.²⁸ Given that the laws are largely similar in structure and

²⁶ Section 1.

²⁷ It is presumed that since the CBD reaffirms the sovereignty, i.e. right of control of nation states over their resources and their power to regulate access, especially to other parties or their citizens, a national authority would be the first point of call for a foreigner seeking access.

²⁸ The Law prohibits the harvesting and/or removal of any forest produce, as defined, without the permit of the relevant authority.

content, the Forestry Law of Lagos State will be used as indicative. “Forest produce” is defined as including “timber, wood oil, fruits, fibres, bark, lac, trees and all other parts or produce of trees, plants and all parts or produce of such plants, and all produce from animals when found in or brought from the forest.”²⁹ This definition is arguably wide enough to include not only the physical biological materials, but also the genetic materials or resources, since it also covers the “parts” and “produce” of plants and animals. The lawmaker might have, as at then, been contemplating only physical products or extracts, and the use of the term “produce” conveys a sense of utility, which in the case of genetic materials confers them with the qualification of “resources”.³⁰ This interpretation, like the aspect of ownership and status is yet untested judicially.

International legal obligations

Nigeria is a party to several international agreements related to or with potential impact on genetic resources, including the CBD, the Convention to Combat Desertification (UNCCD), Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the Ramsar Convention on Wetlands, and the African Convention on the Conservation of Nature and Natural Resources. It has also signed, but not ratified the recently concluded International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Nigeria is also a member of the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

Outside the law governing national parks,³¹ Nigeria has not enacted any laws or regulations that generally govern access to genetic resources or the associated IPRs. Nigeria has signed and ratified CBD and the WTO TRIPS Agreement. However, for the purposes of WTO, Nigeria is classified as a developing country, meaning that it had until 2000 to comply with the provision of Article 27.3(b) of TRIPS. Nigeria has not complied with its obligations under TRIPS to provide for the protection of plant varieties, either by patent or effective *sui generis* legislation or a combination of both.

Most of the existing laws have some bearing on access issues or biodiversity in general. Different government departments and institutions have authority over different aspects of the issues under the various laws, including the trade and intellectual property components. The National Parks Service Decree empowers the National Park Service to implement, in relation to national parks, relevant international treaties, agreements or other arrangements regarding protected areas and wildlife management to which Nigeria is a party.³² Even when many of the other laws contain provisions directly or indirectly affecting access to genetic resources, only the National Park Service Decree explicitly contains benefit-sharing provisions.

Access and benefit-sharing provisions

Any foreign party seeking access to genetic resources within Nigeria should first approach the Ministry of Environment, which has the overall mandate over biodiversity matters in the country. However, the process is neither clear-cut nor straightforward. Several other ministries and agencies have overlapping mandates and could also serve as points of entry in the absence of any specific legislation governing ABS in the country.

Under the National Park Service Decree, the National Park Service is granted exclusive jurisdiction over all national parks with the powers to grant permits for collecting or

²⁹ See Section 2.

³⁰ The CBD defines genetic resources as “genetic material of actual or potential value.”

³¹ National Park Service Decree, No. 46 of 1999.

³² See Section 6 (h).

prospecting for materials in any part of any national park. In this case, jurisdiction as well as administrative requirements for access are clear and specific. Section 36 (1) provides that “no person shall prospect for a genetic material, remove or attempt to remove any biological material from a national park for the purpose of exploiting its genetic material except with the written PIC of the minister on the recommendation of the service.” Subsection (2) states that

“subject to Subsection (1), ... no transfer of a genetic material or indigenous knowledge relating to a genetic material owned or in the possession or custody of a Nigerian citizen, group or association shall be made, except with the written consent of that citizen, group or association, which may be given subject to arrangements being made to share research opportunities and benefits derived from the genetic material or indigenous knowledge relating to the genetic material.”

In addition to the omnibus provisions requiring the permission of the service to enter into or remove any animal or plant from a national park, the decree sets out the conditions for the grant of consent to prospect for genetic resources. These include securing research collaboration with Nigerian scientists; making periodic reports concerning the subsequent use of the genetic resources; and sharing the benefits derived from the resources with the government and people of Nigeria. Furthermore, the obligation to share benefits is stated to be a continuing one and relates to the genetic resources in whatever form they may be synthesized or manipulated, and irrespective of their transfer to other parties.³³ According to the decree, it is an offence to prospect for genetic material, remove biological material, transfer genetic material or related indigenous knowledge, without the required consent. It is noteworthy that the law recognizes and seeks to involve local communities in the management of national parks and sharing of benefits where the local communities border or are located within designated areas.³⁴

The decree provides for the making of regulations for the implementation of its provisions,³⁵ but none have as yet been made. Even when such regulations would have spelled out the step-by-step procedures and requirements for applications in detail, access requests should be fairly straightforward under the current provisions. It would, expectedly, involve a written application to the Conservator-General, who would assess such an application and make a recommendation to the minister charged with the responsibility for matters relating to forestry to grant or refuse consent. There is no information as to whether there have been any applications under the current provisions.

One other interesting aspect of the decree is that there appears to be a distinction between whole animals on the one hand and biological or genetic material on the other. Under Section 31(4), the Conservator-General may issue permits for hunting wild animals within national parks, but under Section 36 permits for prospecting for genetic material or removal of biological material requires the consent of the minister on the recommendation of the Conservator-General. It is not clear whether this distinction is deliberate or inadvertent, but it does set the basis for the determination of what comprises genetic resource for the purposes of access to genetic resources and benefit-sharing within the context of the law.

Outside these provisions, there are no other specific provisions in any other law regarding ABS, except to a limited extent in the Forestry Laws. As also already stated, practically every state in the federation has its own forestry law, and these laws are largely similar in their provisions. Under these laws, the governor of the state may designate specific forest lands as government forest reserves and protected forests. There are also restrictions on access to and

³³ Section 36 (4) (a) – (c).

³⁴ See Sections 47–49.

³⁵ Section 52.

use of biological resources in designated lands or forests. They empower the relevant state authorities to control and make regulations, *inter alia*:³⁶

- prohibiting or regulating the taking of forest produce or any specified kind of forest produce;
- prohibiting the sale and purchase of forest produce or of any specified kind of forest produce by any person other than the holders of licences and permits granted under the law;
- regulating the grant of and prescribing the form that any licence or permit may take in any particular case, to take forest produce in forest reserves, on lands at the disposal of the government, or on communal or other lands, and to sell and purchase forest produce; or
- providing for the collection, payment and disposal of fees, royalties, tolls and costs.

Permits have been and are being granted for logging and hunting purposes, but there is no available information that any permit has yet been granted to prospect for genetic resources *per se*, by any state government, especially as understood under, or within the context of the CBD. Nevertheless, these laws may well be used to govern ABS by granting permits for bioprospecting activities in that regard, especially in view of the definition of “forest produce” in these laws.³⁷

Beyond these instances, there are no formalized procedures for granting consent or permits for access to genetic resources.

Other relevant policies, laws and regulations

There are other laws that affect ABS generally. However, the provisions in the existing laws are basically inadequate – either too vague or too narrow – to effectively address the full range of the relevant issues (Nnadozie 2001). Some of the laws are only aimed at controlling excessive exploitation of the nation’s natural resources, especially its wild fauna, rather than managing access to genetic resources and benefit-sharing as envisaged by the CBD.

The most significant laws are considered below.

The **National Crop Varieties and Livestock Breed (Registration, etc.) Decree**, No. 33 of 1987, which essentially establishes the National Register for Crop Varieties and Livestock Breeds, in which the names of old and new crop varieties and livestock breeds in Nigeria shall be inscribed in a permanent form.³⁸

The **National Agricultural Seeds Decree**, No. 72 of 1992, establishes the National Agricultural Seed Council (the Council) and governs the sale and distribution of seeds, and complements Decree No. 33 of 1987 (regarding crop varieties registration and release). The objectives of Decree No. 72 of 1992 are generally to stimulate the development of a dependable seed industry, regulate and control the registration of released varieties and protect farmers from the sale of poor quality seeds, and to facilitate the production and marketing of high quality seeds in Nigeria. Its objectives are limited to establishing a viable national seed system and ensuring that, for commercial purposes, good quality seeds are available for farmers. It does not include local varieties or landraces which local farmers use on their farms or exchange between themselves. It does not stipulate any requirements, benefit-sharing for instance, where those varieties are used for the development of commercial varieties.

Sea Fisheries Decree, 1992, provides for the control, regulation, and protection of sea fisheries in the territorial waters of Nigeria. Under the decree, no person shall operate or navigate any motor fishing boat for the purpose of fishing within the territorial waters of

³⁶ Forestry Law of Lagos State, Sec. 36.

³⁷ Discussed earlier.

³⁸ Section 1.

Nigeria or its exclusive economic zone, unless that boat has been dully registered and licensed.³⁹ Two regulations have been made pursuant to the decree: the Sea Fisheries (Licensing) Regulations, 1992, and the Sea Fisheries (Fishing) Regulations, 1992. Under the former, the Federal Ministry of Transport is charged with the registration of vessels intended for fishing or shrimping purposes. Under the latter regulations, the Minister of Agriculture is charged with the issuing of licences authorizing a vessel to carry out fishing or shrimping in Nigerian territorial waters.

The **Endangered Species (Control of International Trade and Traffic) Decree**, No. 11 of 1985, was enacted in compliance with Nigeria's obligations under CITES. The federal government promulgated this decree providing for the conservation and management of the country's wildlife and the protection of some of the endangered species in the country. The hunting of, capture of or trade in animal species that are threatened with extinction and are specified in the first schedule of the decree, is absolutely prohibited. Trade in animal species listed in the second schedule to the decree is subject to a licence approved by the relevant minister.

Any person wishing to hunt, trade in, or export any species must apply using the prescribed forms to the Minister for Environment, who determines whether to refuse or grant the permit. It is expected currently that in granting permits, the minister will take into account the objectives of the CBD to ensure the conservation and sustainable use of biodiversity. The primary objective of this law is the protection and conservation of wildlife by prohibiting or restricting hunting and trade, but it also has the effect of regulating access. There is no stipulation on benefit-sharing, except perhaps as is derived from the licensing fees charged on persons wishing to hunt, trade in or export wildlife. The provisions of this law apply to all species specified in the schedules whether they are located on public or private property since no geographic limits were stipulated.

Under Section 1 of the **Land Use Act (LUA)**, 1978, all land in the territory of each state is vested in the governor of that state, and such land shall be held in trust and administered for the use and common benefit of all Nigerians. The governor can grant as well as revoke either a certificate of occupancy or rights of occupancy to individuals or groups for use and enjoyment.⁴⁰ Provisions of the LUA, suggest that the states control all the biological diversity within their territories, although no specific reference is made to biological diversity. LUA removes absolute ownership of land from the citizens, recognizes communal and family forms of tenure which are derived from customary rights of occupancy and confer control, the right to use and enjoy land, or alienate the same according to customary laws and practices. Under this regime, nonetheless, communities can only have customary rights of occupancy, which are subject to the overriding title of the state

Intellectual property rights

The principal law governing the protection of intellectual property as it may relate to biodiversity is the Patents and Designs Act.⁴¹ It expressly prohibits the granting of patents in respect of "plant or animal varieties, or essentially biological processes for the production of plants or animals other than microbiological processes and their products."⁴² Also, patents cannot be issued for inventions for which the publication or exploitation would be contrary to public order or morality.

³⁹ Section 1(1).

⁴⁰ See Sections 5 & 28.

⁴¹ Cap 344 Laws of the Federation of Nigeria.

⁴² Section 1(4) (a) and (b) of the Patents and Designs Act, cap. 344, Laws of the Federation of Nigeria (LFN), 1990.

Patent protection is not currently available for plant varieties and no other *sui generis* protection has been provided for them as would be required by Article 23.3(b) of TRIPS. There is also no formal recognition or legal protection accorded to the knowledge and innovations of local communities and farmers in respect of biodiversity, because no law has yet been enacted in that regard as envisaged by Article 8(j) of the CBD.

New initiatives or pending legislation related to ABS

The existing legislation in Nigeria is generally inadequate to meet current situations and emerging conceptual and technical developments, as well as to comply with existing and accruing international obligations. Efforts have been made to review and update existing legislation to address these shortcomings and also take into account public policy issues, especially the social and economic development needs of the countries.

In 2002, in view of the urgent need to review and update the substantive laws on intellectual property, attempts were made to provide for recent developments and ensure compliance with the requirements of TRIPS Agreement. The Ministry of Commerce inaugurated a task force to fashion the necessary framework for the establishment of a National Intellectual Property Commission as a body to effectively administer intellectual property law. The task force prepared a draft bill for the structure and institutional arrangement for the proposed Intellectual Property Commission and in respect of all categories of industrial property rights – patents, trademarks, industrial design – including, for the first time, plant variety protection. The draft bills have already undergone extensive stakeholder review and are currently awaiting the approval of the National Executive Council before being forwarded to the national assembly for consideration and enactment into law.

Access requests and decisions: pre-legislation and CBD

Activities related to access to genetic resources in Nigeria are carried on by a broad range of actors, including individuals and researchers, government and public institutions, and international corporations and organizations. However, as a result of the largely unregulated state of affairs and the informal nature of the relevant activities, getting specific information and details of these activities is generally difficult. This is further exacerbated by the sheer size and diversity of the country. It covers a total land area of 910 770 km² and has a population of over 120 million, with over 250 distinct ethnic groups, speaking over 300 different languages. Nigeria has more than 15 Federal Agricultural Research Centres, over 40 universities, together with other institutions of higher learning. Most of these carry out research or collaborative activities. Hence, getting accurate data or any general information is a challenge. Any assessment of previous and ongoing bioprospecting activities can, at best, be only partial and the data approximate. A few instances have been noted, but there are no official records of or reliable data on private sector bioprospecting initiatives and activities.

There has only been one formal application for a permit submitted to the Federal Ministry of Environment (which is the national focal point for biodiversity matters). This application was dealt with on an ad hoc basis. Details are not readily available, although the Ministry of Environment tried to involve other ministries, as well as experts, in developing modalities for assessing applications and granting permits. However, it would appear that the consent process did not reach a logical conclusion, ostensibly because the applicant was unwilling to meet some of the requirements or decided to follow the easy way out, by resorting to open or unauthorized access to the materials it needed.

The National Institute for Pharmaceutical Research and Development (NIPRD) is one of the public institutions engaged in active bioprospecting and related activities for both research and commercial purposes. It focuses on developing drugs and natural products from biological resources and works closely with traditional medical practitioners. In the

absence of any regulations for ABS, NIPRD seeks to comply with the CBD objectives of sustainable use and equitable sharing of derived benefits with providers of genetic resources and knowledge holders. NIPRD has developed a standard agreement with herbalists and traditional healers who provide samples and materials for further research and development. The agreement provides an explicit and comprehensive framework for obtaining informed consent of the local herbalist for using their knowledge to develop commercial products, as well as sharing the benefits accruing from the research.

One of the earliest private sector actors in bioprospecting activities, at least within the context of the CBD, in Nigeria, was Shaman Pharmaceuticals Inc., a USA-based company that focuses on drugs from natural products. Most of its prospecting activities were based on ethnomedicine and therefore it worked very closely with herbalists and university researchers. It operated through or in collaboration with local Nigerian firms and institutions, which included the Guild of Herbalists, the Bioresources Development and Conservation Programme (BDCP), and the University of Nigeria, Nsukka. Shaman Pharmaceuticals collects samples of medicinal plants through these collaborations, for screening. Some of the preliminary evaluation is done in the collaborating university and centres, although most of the time, the samples are taken to the USA for advanced screening. Shaman Pharmaceuticals obtained plant research permits through the National Agency for Scientific and Engineering Infrastructure in Lagos, a unit within the Federal Ministry of Science and Technology.⁴³ The permits enabled it to undertake ethnobotanical surveys and collection expeditions, as well as to export samples of material collected.⁴⁴

BDCP is also carrying out its own bioprospecting activities in respect of medicinal plants. It seeks to combine conservation objectives with commercial activities and maintains a network of relationships, spanning from government agencies, local and public institutions, international organizations, to the private sector. It is primarily focused on discovering medically active plants for drug development – both independently as well as under the

⁴³ The National Agency for Science and Engineering Infrastructure (NASENI) was established by Decree 33 of 1992. Under Section 6(2)(d), its functions include the development of facilities and capabilities, inter alia, for "(iii) development-oriented research in agriculture and forestry environmental conservation, fisheries and animal husbandry, nutrition, human and veterinary medicine, pharmaceutical materials and building and construction materials; (iv) collaboration with higher educational institutions and other relevant government institutions, organizations, agencies and commercial industries in the research and development of capital goods... . Section 8 empowers the Board of the Agency to enter into research and production partnerships with any company, firm, or individual, as may be necessary, for the performance of the functions of the Agency."

⁴⁴ It may be argued that, since there are no specific laws or regulations governing access in Nigeria, the power to grant the permit is read into the law establishing the Agency, especially the provisions empowering it to collaborate with other entities. This organic law, however, did not distinguish between national and foreign collaborators and thus establishes another apparent situation of jurisdictional overlap with that of FEPA (Ministry of Environment) in terms of ABS issues.

International Cooperative Biodiversity Group (ICBG).⁴⁵ In the absence of specific regulations for obtaining permits, most of its collecting activities are carried out in conjunction with or with the consent of government agencies, for instance, the National Agency for Science and Engineering Infrastructure, through which the ICBG also obtains permits for collection.

Main legal issues and conclusions

The most obvious legal challenge to ABS in Nigeria is the politico-legal system itself – that is the federal structure in which it operates. The stakeholders have not even started grappling with the complexities that are inherent in and immanent from it. At some point the many and varied issues would have to be confronted and some form of resolution arrived at, because they are evolving rapidly at the international level. There is an urgent need to set the framework that will address them.

The federal government may have the undisputed powers to regulate IPRs and international aspects or transactions involving foreign parties. However, the physical entry into land and collection of biological materials can only be carried out through or with the consent of the individual state authorities in whose territory the materials are located and or the individual or community in possession or control of the land.

There is lack of capacity for implementing and enforcing of existing regulations, and awareness among government officials of the dimensions and debates on the use and conservation of genetic resources, especially at the international level.

It is essential to adopt legal and policy measures in respect of genetic resources in order to effectively address the existing challenges and emergent problems. A coordinated and multisectoral approach needs to be adopted involving the different levels of governance, all the relevant sectors and stakeholders. This must be done in conjunction with the provision of adequate resources to implementing and training institutions to carry out the relevant administrative, research and capacity enhancing activities.

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⁴⁵ The International Cooperative Biodiversity Group (ICBG) is a multi-institutional project involving the Walter Reed Army Institute of Research, U.S. National Institutes of Health (NIH), USA National Science Foundation (NSF), and U.S. Department of Agriculture (USDA). It is funded through an interagency agreement sponsored by USA organizations, the NIH, NSF and USAID. The main focus of the African ICBG project is the establishment of an integrated programme for the discovery of medicinally active plants for drug development and the conservation of biodiversity. It ensures that local communities and source countries derive maximum benefits for their biological resources and intellectual contributions. Selected plant products will be developed to preclinical stages before negotiation with commercial partners. Future royalties from such products will presumably be distributed through an independent legal trust fund consisting of representatives from the United States of America, Cameroon and Nigeria. Revenues generated by this project are also expected to be used solely for projects that promote conservation of biological diversity, drug development and economic well-being of the communities that provided the resources.

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7. South African legislative case study⁴⁶

Rachel Wynberg

Introduction

South Africa is actively engaged in bioprospecting for natural product development for commercial gain.

This is due largely to the country's extraordinarily rich and unique biodiversity⁴⁷ and well-developed research and institutional capacity.

A 1996 review on bioprospecting in South Africa showed that virtually every research institution in South Africa is involved in bioprospecting activities, some formally and others more covertly (Laird and Wynberg 1996). Since then, approaches to bioprospecting in South Africa have become far more sophisticated and transparent, although this has not been without burnt fingers. An agreement between the National Botanical Institute and Ball Horticulture, for example, raised the public ire for purportedly 'selling off the family silver' (Wynberg 2003; Henne and Fakir 1999). Use of the San's TK of the succulent plant *Hoodia* in development of an anti-obesity drug, and the patenting by the CSIR of active constituents of the plant, captured international attention due to the neglect of the CSIR to obtain the PIC of the San. It also led to one of the first benefit-sharing agreements to give indigenous communities a share of royalties from drug sales. Other less controversial, but by no means less significant, agreements have also built broad understandings and capacities about how to "do the right thing" to overcome the key constraints that prevent bioprospecting from being a useful tool for conservation and development.

Legal status of genetic resources

South Africa's Constitution (Act 108 of 1996) provides a central framework for biodiversity management in South Africa, including the respective powers of national, provincial and local spheres of government. Through the Constitution, national government and the nine provinces are accorded concurrent legislative competence in biodiversity conservation⁴⁸. These include such areas as agriculture, environment, nature conservation, pollution control, regional planning and development, soil conservation, urban and rural development, and tourism. The Constitution also demarcates several relevant areas as being of exclusive national competence, such as national parks, botanical gardens and marine resources; and provincial jurisdiction, such as provincial planning. It provides for the administration of certain functions at the local government level, such as beaches and municipal parks. Chapter 3 of the Constitution emphasizes the notion of cooperative government and reflects a fundamental departure from the past in that the three traditional spheres of government – national, provincial and local – are no longer regarded as hierarchical tiers with national government at the helm, but rather as three "distinctive, interdependent and interrelated" spheres of government.

Genetic resources and their ownership are not explicitly considered by the Constitution, and legal clarity on this issue remains unresolved. Chishakwe and Young (2003) remark that,

⁴⁶ Editors note. Between the time of writing and publication, the Biodiversity Act has come into force and a draft of implementing regulations on access and benefit sharing has been developed. These should therefore be considered supplemental to the discussion in this paper.

⁴⁷ In the plant kingdom alone, at least 80% of the 18 000–20 000 species are known to be endemic. Intraspecific genetic diversity is also unusually high, adding to the potential for developing new medicines, crops, cosmetics, ornamental plants and other useful products.

⁴⁸ Schedules 4 and 5, respectively.

“no country has yet found or developed a workable legal framework that clarifies who owns genetic resources, partly because of the difficulties of defining ‘genetic resources’ and the lack of legal understanding on the matter”. South Africa is no exception, although the property clause in its Bill of Rights is potentially relevant, more especially because much of South Africa’s biodiversity falls within private ownership. The clause provides that no one may be deprived of property unless this is in terms of a law of general application, and is not arbitrary⁴⁹. Property may be expropriated only for a public purpose, or in the public interest, and is subject to compensation. Under South African common law, a landowner owns everything beneath and above the land. This includes plants but excludes wild animals, which are considered *res nullius* (owned by nobody). South African common law does not grant a property rights’ holder an inherent right to compensation for denial of, or restrictions on, the use to which property is put (Glazewski 2000). It could be argued that while the state through legislation is empowered to introduce regulations to achieve biodiversity conservation and sustainable use, any regulation imposing restrictions on ownership of genetic resources would probably not require the original owners of those resources to be compensated, because it would be regarded as a deprivation rather than an expropriation (Kidd and Mayet 2003).

Several categories of land ownership exist in South Africa, characterized by a broad division between freehold or western notions of ownership and customary approaches to land ownership. Most state land and white commercial agricultural land is held under freehold, while land under customary tenure falls within the so-called ex-homelands, which together comprise 13% of the country, and are home to some thirteen or so million inhabitants. While statutory laws apply in both circumstances, in communal areas a layer of customary law also applies, and this is frequently the system best understood and implemented by communities living in the area. In communal areas, customary laws form a central component of the practice of natural resource use. Where traditional systems are in tact, strong cultural taboos exist – and have long existed to regulate the use of particular resources. No distinction is made between genetic resources and natural resources, although certain resources are accorded different levels of protection.

Customary tenure systems comprise a myriad of forms (Cross 1991), including:

- communal tenure, which generally takes the form of sharing of land in a system run by chiefs;
- trust tenure, which originates from the system of ‘betterment’ imposed by colonial rulers to restrict black ownership of land;
- quitrent tenure, which is a form of individual tenure that gives permanent possession of the land to the registered holder in return for annual payment of a nominal rent; and
- leasehold, which comprised the basis for individual tenure rights for blacks in apartheid South Africa.

Many residents of communal areas are victims of the apartheid government’s policy of separate development, which entailed the forced removals and relocation of people to pockets of land considered marginal for agriculture or mineral development. Through years of apartheid policies, community identity and organization have been undermined, or come into conflict with state-appointed tribal authorities or newly emerging local government structures (Ntsebeza 1999). The frequently conflicting jurisdiction of traditional authorities and political or administrative representatives of the state further complicates matters, and results in many cases in an administrative vacuum.

A major problem in the former ‘homeland’ areas is the lack of adequate legal recognition of communal tenure systems and traditional resource management and rights. Attempts to

⁴⁹ Section 25(1).

redress this situation have recently been made in the long-awaited Communal Land Rights Act (11 of 2004), which sets out the government's approach to communal land tenure reform and traditional land rights (Republic of South Africa, 2004). The 1996 Communal Property Associations Act (CPA Act) also aims to provide for communally held tenure through enabling people to acquire and manage property as groups. Both proposals have met with little enthusiasm, mainly because of their inappropriate adoption of the titling model, based on western notions of ownership, and in the case of the CPA Act, because of the limited support provided by government in the establishment of CPAs and community trusts (Cousins 2002). This context has relevance, not so much in terms of the definitional issues around genetic resources, but with respect to the implementation of ABS legislation and realization of benefits that may accrue to communities.

It has been noted by critics that considerable ambiguity exists with respect to the definition used for "genetic resources" (see, for example, Nnadozie et al. 2003). Such ambiguities are reflected in South Africa's recently promulgated Biodiversity Act 10 of 2004, which, in Section 1, defines "genetic resources" as including, any genetic material⁵⁰ or the genetic potential or characteristics of any species.

The only place in which this definition is in fact used is in Section 3 of the Act dealing with the state's trusteeship of biological diversity, which states:

"In fulfilling the rights contained in Section 24⁵¹ of the Constitution, the state through its organs that implement legislation applicable to biodiversity, must:

- a) manage, conserve and sustain South Africa's biodiversity⁵² and its components and genetic resources; and
- b) implement this Act to achieve the progressive realization of these rights."

The relevance and wording of this clause was the subject of intense debate in the development of the Act, largely because of concerns that it may conflict with Constitutional obligations with respect to private ownership of land. However, this compromise text does little to clarify the legal status of genetic resources.

More significantly, Chapter 6 of the Biodiversity Act, entitled "Bioprospecting, Access and Benefit-Sharing", sets out the framework for the regulation of ABS in South Africa and provides greater guidance with respect to the scope of the legislation.

The purpose of Chapter 6 is to:⁵³

- regulate bioprospecting involving indigenous biological resources;
- regulate the export from the Republic of indigenous biological resources for the purposes of bioprospecting or any other kind of research; and
- provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

⁵⁰ In terms of the Act, 'genetic material' means any material of animal, plant, microbial or other biological origin containing functional units of heredity. This corresponds with the definition used by the Convention on Biological Diversity.

⁵¹ Section 24 declares that. "Everyone has the right: to an environment that (a) is not harmful to their health or well-being; and (b) to have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that (i) prevent pollution and ecological degradation; (ii) promote conservation; and (iii) secure ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

⁵² The definition used for "biodiversity" is that of the CBD, which *inter alia* includes genetic resources.

⁵³ Section 80.

Indigenous biological resources are interpreted widely to include any:

- living or dead animal, plant or other organism of an indigenous species;
- derivative of such animal, plant or other organism; or
- genetic material of such animal, plant or other organism;

This applies to:

- resources gathered from the wild or accessed from any other source, including any animals, plants or other organisms of an indigenous species cultivated, bred or kept in captivity or cultivated or altered in any way by means of biotechnology;
- any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to earlier in subparagraph (i); or
- any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms referred to in subparagraph (i) or (ii).

Material of human origin is excluded from the ambit of the law, as are exotic organisms and indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

International legal obligations

South Africa is signatory to a range of international instruments of relevance to the conservation and use of genetic resources. These are described in Table 7.1, together with an overview of policies and laws put in place to implement treaty obligations. South Africa, represented by DEAT, is also a member of the “like-minded, megadiverse” coalition, representing 15 of the most biologically diverse countries in the world.⁵⁴

Access and benefit-sharing with respect to national and provincial policies and laws

A plethora of national policies and laws have relevance for ABS, but only recently has there emerged a more coherent and specific regulatory framework for ABS, encapsulated in the Biodiversity Act. Indeed, the absence of a legal framework for ABS in South Africa is widely considered to have been a major reason for the failure so far of bioprospecting to deliver optimal benefits in the country (See, for example, Wynberg 2003, Glazewski et al. 2001). Table 7.2 provides a description of policies and laws in South Africa with relevance for ABS. A key point to emphasize is that South Africa is currently in a transition with respect to ABS, and new legislation encapsulated in the Biodiversity Act has yet to be fully implemented. Regulations on ABS will, however, be gazetted in 2006.

⁵⁴ The so-called Group of Like-Minded MegaDiverse Countries comprises Bolivia, Brazil, China, Colombia, Costa Rica, Ecuador, the Philippines, India, Indonesia, Kenya, Malaysia, Mexico, Peru, South Africa and Venezuela. The Group was formally constituted through the Cancun Declaration of February 18, 2002 as a “consultation and cooperation mechanism” to promote common interests and priorities related to the conservation and sustainable use of biodiversity. The development of an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources has been adopted by the group in its action plan as one of five areas of priority and action. See also www.megadiverse.org

Table 7.1 International agreements of relevance to the conservation and use of genetic resources in the Republic of South Africa.

Agreement	South Africa's Status	Implementation	Responsible department
Convention on Biological Diversity (CBD)	Became a party to the Convention on 2 November 1995	White Paper on the Conservation and Sustainable Use of Biological Diversity (1997). Biodiversity Act of 2004. Protected Areas Act (57 of 2003). A wide range of related policies and laws already exist to implement the CBD (see Table 7.2).	Department of Environmental Affairs and Tourism (DEAT)
Cartagena Protocol on Biosafety (under the CBD)	Became a party to the Protocol on 14 August 2003	GMO Act (15 of 1997) is currently under review to enable implementation of the Protocol. A GMO Amendment Bill was due to be ratified by Parliament in 2006.	DEAT & National Department of Agriculture
International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	In the process of ratifying the agreement. A draft implementation strategy for the ITPGRFA has been prepared.	Implementation of the IT in South Africa is still embryonic. However, the Biodiversity Act covers broadly ABS with respect to indigenous biological resources. Farmers' rights and <i>in situ</i> conservation remain major implementation gaps.	National Department of Agriculture
TRIPS Agreement of the World Trade Organization	South Africa is a member organization of the WTO	Through the Plant Breeders Act, South African law is considered compliant with Article 27 3(b) of TRIPS, requiring plant variety protection. The South African patent law developed from the British equivalent, is currently TRIPS compliant in that it allows for the patenting of microorganisms, but not for plants and animals. Both laws are somewhat dated and were developed prior to TRIPS and South Africa's democracy. Moreover, a number of issues relating to the interface between TRIPS and the CBD have not yet been resolved at national level. These include the disclosure of origin for patent applications; TK protection; and approaches towards the patenting of life.	Department of Trade and Industry; National Department of Agriculture; DEAT; Department of Health
International Convention for the Protection of New Varieties of Plants (UPOV Convention)	South Africa has signed but not ratified the 1991 version of this agreement. South Africa has also signed the 1978 version of UPOV, upon which current legislation is based.	UPOV 1978 is implemented through the Plant Breeders' Right Act 15 of 1976 and the Plant Improvement Act 53 of 1976.	National Department of Agriculture
Patent Cooperation Treaty	South Africa became a member state of the PCT on 16 March 1999.	Intellectual Property Laws Amendment Act 38 of 1997.	Department of Trade and Industry
International Plant Protection Convention (IPPC)	Ratified by South Africa in 1995.	Agricultural Pests Act provides measures to control phytosanitary risks.	Department of Agriculture

Many of the policies and laws have relevance to ABS, but two in particular deal specifically with the matter.

The 1997 Biodiversity White Paper (DEAT 1997) was the first national policy to chart South Africa's policy on access to genetic resources and benefit-sharing, and emerged following a two-year period of public consultation (Wynberg and Swiderska 2001). A comprehensive research process, led by the Land and Agriculture Policy Centre, formed the basis for the policy formulations, and included interviews with over 50 people, representing a variety of sectors.

ABS is included as one of the six key goals of the Biodiversity White Paper, which aims to "ensure that benefits derived from the use and development of South Africa's genetic resources serve national interests." Two objectives support the goal:

- control access to South Africa's indigenous genetic resources through the introduction of appropriate legislation and establishment of institutional structures; and
- ensure continued access to sources of genetic material for food, agriculture and forestry.

The first objective includes:

- developing detailed guidelines and conditions for bioprospecting;
- developing an efficient permit system for the collection of resources and minimum requirements for benefit-sharing;
- promoting collaboration and cooperation between research institutions;
- establishing a system of disbursing funds;
- minimizing impacts on the environment at collecting; and
- developing a system to provide legal protection for collective rights.

Within the second objective, South Africa is committed to participate in:

- the revising of the (then) International Undertaking on Plant Genetic Resources;
- the initiating of a national process to develop and implement legislation on farmers' rights; and
- supporting activities to protect indigenous and traditional livestock breeds and plant varieties.

Importantly, the White Paper states as a priority action the need to establish legislative and administrative mechanisms to control access to South Africa's genetic resources. Currently, a process is underway to develop South Africa's National Biodiversity Strategy and Action Plan. This was finalized in October 2004, and includes equitable benefit sharing as a specific strategic objective.

Following on from the Biodiversity White Paper, and seven years in the making, South Africa's Biodiversity Act was finally promulgated in 2004. The framework legislation broadly covers all areas of biodiversity conservation and use, with ABS comprising one of ten chapters. The objectives of the Act are within the framework of the National Environmental Management Act, to:⁵⁵

- a) manage and conserve biological diversity within the Republic and of the components of such biological diversity;
- b) provide for the use of indigenous biological resources in a sustainable manner; and
- c) provide for the fair and equitable sharing among stakeholders of benefits arising from bioprospecting involving indigenous biological resources.

⁵⁵ Section 2.

Table 7.2 Key national and provincial policies and laws of relevance to biodiversity access and benefit-sharing in the Republic of South Africa.

Policy or Law	Content	Responsible Institutions
Policies		
White Paper on Environmental Management Policy (1999)	Sets out a vision, policy principles and strategic goals for environmental management and the sustainable use of natural resources in South Africa. Sectoral policies must conform to this policy.	DEAT is identified as the lead agent for environmental management
White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity (1997)	The policy and strategy sets out a vision, mission and principles for biodiversity management. Six goals are identified, together with supporting objectives. Goal 3 aims to ensure that benefits derived from the use and development of South Africa's genetic resources serve national interests.	DEAT is the lead institution. Several other national, provincial, and local government departments are responsible for various aspects of implementation.
Policy for Sustainable Forest Development in South Africa (1996)	Aims to promote a thriving forest sector, to be used for the benefit of the nation, and develop and manage the environment.	DWAF; provincial environmental and conservation departments
Marine Fisheries Policy for South Africa (1997)	Strives to improve the overall contribution of the fishing industry to a competitive fast-growing economy. The economy creates sufficient jobs for all work sectors and a redistribution of income and opportunities in favour of the poor. This includes sustainability as one of its key objectives. It makes provision for the designation of marine protected areas.	DEAT (Marine and Coastal Management) is responsible for fisheries administration, research, and the protection of marine resources. MCM is also responsible for issuing permits relating to the collection of marine resources for bioprospecting.
Indigenous Knowledge Systems Policy (2004)	Is an enabling framework to stimulate and strengthen the contribution of indigenous knowledge to social and economic development in South Africa.	Department of Science and Technology, supported by an advisory committee that reports to the Minister. Legislation to protect intellectual property associated with indigenous knowledge, to be administered by the Department of Trade and Industry.
Laws		
Constitution of the Republic of South Africa (Act 108 of 1996)	Conservation and ecological sustainability are given prominence in the Bill of Rights.	National and provincial government are accorded concurrent legislative competence in terms of most functions of relevance to biodiversity conservation. National Parks, botanical gardens, and marine resources are however, an exclusive national competence.
National Environmental Management Act (107 of 1998)	Gives legal effect to the Constitution and to the White Paper for Environmental Management. Sets in place procedures and mechanisms for cooperative governance.	DEAT is the lead agent. The Act establishes a National Environmental Advisory Forum (yet to be constituted) and the Committee for Environmental Coordination.
Environmental Conservation Act (73 of 1989)	Provides for the protection and control of activities that may have a detrimental effect on the environment and is concerned primarily	DEAT; provincial environmental and

Table 7.2 Key national and provincial policies and laws of relevance to biodiversity access and benefit-sharing in the Republic of South Africa.

Policy or Law	Content	Responsible Institutions
1989)	with environmental impact assessments.	conservation departments
National Forests Act (84 of 1998)	Overall purposes include the sustainable use, management and development of forests; the restructuring of state forestry; the protection of certain forests and trees; the promotion of community forestry; enhanced participation. Certain activities may be licensed in state forests, including the collection of biological resources. ⁵⁶	DWAF; National Forests Advisory Council; National Forest Recreation and Access Trust; Provincial environmental and conservation departments. A National Forests Advisory Council advises the minister on any matter related to forestry in the Republic ⁵⁷ .
The Genetically Modified Organisms Act (15 of 1997)	Controls the development, production, use and application of genetically modified organisms.	National Department of Agriculture. The Act establishes an Executive Council as the main decision-making forum, and an Advisory Committee to provide expert input.
Marine Living Resources Act (18 of 1998)	Provides for the conservation of marine ecosystems, the sustainable use of marine living resources and for orderly and equitable access to such resources. No person shall undertake commercial fishing or subsistence fishing, engage in mariculture or operate a fish processing establishment unless a right to undertake or engage in such an activity or to operate such an establishment has been granted by the minister. ABS is not explicitly covered by the Act, but existing recreational permits could allow sufficient quantities to be legally removed for analysis. Exemptions are granted for a number of activities, including research, and could be used for bioprospecting purposes.	DEAT (marine and coastal management). A Consultative Advisory Forum is established to advise the minister.
Conservation of Agricultural Resources Act (43 of 1983)	Provides for the conservation of agricultural resources. New regulations introduce strict controls for invading plant species. The Draft Sustainable Utilization of Agricultural Resources Bill, 2003 has been compiled by the Department of Agriculture with a view to repeal CARA.	National and provincial Departments of Agriculture.
National Environmental Management: Protected Areas Act (57 of 2003)	Aims to consolidate and rationalize existing legislation dealing with protected areas, and to bring the system of protected areas in line with the new constitutional and legal order, and new policies and programmes of the Government. The Act provides for the establishment of a representative system of protected areas and the participation by communities in conservation and its associated benefits, and for cooperative governance in the management of protected areas ⁵⁸ .	–
Biodiversity Act of 2004	Provides for the management and conservation of South Africa's biodiversity within the framework of the National Environmental Act, 1998; the protection of species and ecosystems that warrant national protection; the sustainable use of indigenous biological resources; the fair and equitable sharing of benefits arising from bioprospecting of genetic material derived from indigenous biological resources; and the establishment and functions of a South African National Biodiversity Institute.	–

⁵⁶ Section 23 (b, e, f, j and k).

⁵⁷ Ss 2(a, b, c and g).

⁵⁸ National Environmental Management Protected Areas Bill, general background and overview.

Table 7.2 Key national and provincial policies and laws of relevance to biodiversity access and benefit-sharing in the Republic of South Africa.

Policy or Law	Content	Responsible Institutions
Agricultural Pests Act 36 of 1983	Provides for the prevention and combating of agricultural pests, and regulates the importation of controlled goods. Prohibits any person from importing into South Africa any plant without a permit. The minister has imposed a number of controls concerning the import of seeds by requiring phytosanitary certificates.	–
Patents Act 57 of 1978	The purpose of the act is to provide for the registration and granting of patents for inventions and matters connected therewith. It provides for the patenting of microorganisms and microbiological processes, but prohibits the patenting of plants and animals.	Department of Trade and Industry
Patents Amendment Bill	Amends the Patents Act, 1978, so as to require an applicant for a patent to furnish information relating the use of indigenous biological resources or traditional knowledge in an invention.	Department of Trade and Industry
The Plant Breeders' Rights Act 15 of 1976	Provides a system for the protection and registration of the rights of certain breeders to prescribed varieties of plants. The Act includes the notion of 'farmers' privilege' for seed-saving but does not provide for farmers' rights.	National Department of Agriculture
Plant Improvement Act 53 of 1976	Provides a framework for the sale of certain plants and the cleansing, packing and sale of certain propagating material.	National Department of Agriculture
Animal Improvement Act 62 of 1998	Provides for the breeding, identification and use of genetically superior animals in order to improve the production and performance of animals.	National Department of Agriculture
Agricultural Pests Act 36 of 1983	Includes restrictions on the importation of controlled goods, which include plants, pathogens and insects. ⁵⁹	National Department of Agriculture
Various Provincial Ordinances and Acts	28 legal instruments for nature conservation exist at the provincial level. In general they allow for the establishment and protection of nature reserves, for the conservation of threatened species, and for fishing and hunting. Many of these laws are outdated and the nine provinces are at different stages of phasing out old laws and developing and implementing new ones.	Provincial Environmental Conservation Departments
Traditional Health Practitioners Act 35 of 2004	To provide a regulatory framework to ensure the efficacy, safety and quality of traditional health care services.	Department of Health

An important rationale for the Biodiversity Act is to resolve the fragmented nature of biodiversity-related legislation at national and provincial levels, and to consolidate different laws⁶⁰. A key aspect is to realize the management policy of the *White Paper on Environmental Management*, with its emphasis on the principle of cooperative governance to ensure that the environmental rights in the Constitution are protected and fulfilled. The Act forms part of the implementation of the overarching National Environmental Management Act (NEMA) 107 of 1998, and is to be applied in furtherance of any applicable provisions⁶¹ and principles set out in NEMA.⁶²

Chapter 6, entitled 'Bioprospecting, Access and Benefit-Sharing', sets out the framework for the regulation of ABS in South Africa. Its purpose is to:⁶³

- a) regulate bioprospecting involving indigenous biological resources;

⁵⁹ Section 3(1)(a).

⁶⁰ Memorandum on the objects of the National Environmental Management: Biodiversity Act.

⁶¹ Section 6(1).

⁶² Section 7.

⁶³ Section 80.

- b) regulate the export from the Republic of indigenous biological resources for the purposes of bioprospecting or any other kind of research; and
- c) provide for a fair and equitable sharing by stakeholders in benefits from bioprospecting involving indigenous biological resources.

The Act requires that permits be obtained for all bioprospecting projects, and the export of any indigenous biological resource to be used for bioprospecting or any other kind of research. Those providing access to resources or knowledge, or whose “traditional uses” form part of the bioprospecting, must be consulted and their prior consent obtained before a permit is issued. This should be on the basis of all material information being disclosed. The Act distinguishes between procedures to obtain indigenous biological resources; and those to obtain knowledge. A Material Transfer Agreement (MTA) is required for indigenous biological resources between the applicant and “stakeholder”, as well as a benefit-sharing agreement, prior to permit issuance. A benefit-sharing agreement is required for holders of knowledge. Ministerial approval of all benefit-sharing or material transfer agreements is required. Those issuing permits may facilitate negotiations between the applicant and stakeholder to ensure these are on an equal footing, or may be required by the minister to ensure the arrangement is fair and equitable.⁶⁴

Very broad requirements for benefit-sharing agreements and material transfer agreements are set out⁶⁵ and a Bioprospecting Trust Fund is established into which all moneys arising from agreements must be paid, and from which all payments to stakeholders would be made.⁶⁶ Benefit-sharing agreements must be in a prescribed format and must specify the type and quantity of resources to be collected, the area of collection, traditional uses of the resources, and potential uses. Agreements must set out the manner in which the resources are to be used and the extent to which stakeholders will share in benefits. Material transfer agreements must be in a prescribed format and set out the particulars of the provider and recipient, the type and quantity of resources to be provided, the area of collection, the purpose for export, potential use, and conditions for transfer to a third party.

The Act provides for the developing of regulations on the form, contents, requirements and criteria for benefit-sharing agreements and material transfer agreements; moneys payable in connection with these agreements; and the administration of the Bioprospecting Trust Fund. One year is allowed for current bioprospecting projects to develop benefit-sharing agreements as stipulated. The Act also establishes the South African National Biodiversity Institute (SANBI), which replaces the current National Botanical Institute. SANBI manages and controls the botanical garden, *ex situ* collection, biodiversity research and information, and coordinates ecosystem rehabilitation and invasive species management. Noteworthy is the exclusion of ABS from the mandate of SANBI, in response to concerns about this institution’s involvement in bioprospecting and therefore the potential for conflicting interests.

Governance and the institutional framework for access and benefit-sharing in South Africa

To a large extent, the institutional framework within which South Africa’s biological resources are controlled and managed reflects the fragmented legal environment described earlier. This is aggravated by the fact that several of South Africa’s nine provinces – and more especially those located in the erstwhile ‘homeland’ areas – are still in the process of integrating their administration and laws. The lead institution charged with administering

⁶⁴ Section 82(4b) and (4c)

⁶⁵ Sections 83 and 84 respectively

⁶⁶ Section 85

the CBD and in formulating national norms and standards for biodiversity management in South Africa is the national DEAT. It takes a central role in setting the national framework for ABS and, as is envisaged in the Biodiversity Act, will be responsible for formulating norms and standards for benefit-sharing agreements and material transfer agreements. Historically, however, DEAT has played a near absent role in providing policy guidance in steering agreements towards an equitable and optimum outcome.

ABS issues typically straddle a variety of different departments such as Environmental Affairs and Tourism, Trade and Industry, Arts and Culture, Science and Technology, Health, and Agriculture. The potential for overlap of mandate thus exists, more especially in the implementation of international agreements as exemplified by DEAT's responsibilities for administration of the CBD, and the National Department of Agriculture's responsibility for implementation of the ITPGRFA. Provisions of the Biodiversity Act incorporate all indigenous biological resources, but exclude those listed in terms of the ITPGRFA. A detailed legislative and institutional audit has to be done in the implementing of the ITPGRFA. Farmers' rights in particular are a key legislative gap but, as is the case with indigenous and TK, their protection has proved extremely complex. An "in principle" intent exists to realize these rights through legal protection, but in practice the process has been thwarted by a mix of capacity constraints ("the issue is too big and complex"), a poor understanding of this rapidly evolving field, especially with respect to implementation; and difficulties in marrying the different economic and social realities of South Africa (e.g. a highly developed commercial plant breeding sector and an underdeveloped and poorly organized small-scale farming component).

In terms of current decision-making for ABS, prior to the implementation of the Biodiversity Act, at a broad political and strategic level, Cabinet and the Director-General clusters remain responsible for decision-making across national departments, in addition to the Committee for Environmental Coordination (CEC) established, based on Chapter 2 of NEMA. The CEC consists of the Directors-General of ten national departments, the heads of provincial environmental departments, as well as a representative from local government. Specific issues relating to biodiversity and heritage are considered by a working group established under MINTEC, a technical committee set up to support the work of MINMEC, which is a ministerial forum constituted to address concurrency issues between national and provincial government. Focused committees are also constituted under the Biodiversity and Heritage Working Group.

ABS is an important mandate of the Biodiversity and Heritage Working Group, with the result that several provinces have now adopted a standard Memorandum of Understanding (MOU). It was developed by the National Botanical Institute with assistance from Kew Botanical Gardens, to guide the negotiations of third parties requesting access to certain genetic resources. The MOU is designed for the collection of biological material for research, prohibits use of the material for commercial purposes and prevents transfer to third parties. For commercial purposes, the applicant is required to develop a separate agreement with the provider of the biological material.

Also of relevance is the South African National Plant Genetic Resources Committee, established by the Department of Agriculture in 1996, as a counterpart to the SADC Plant Genetic Resources Centre, and in parallel with the establishment of similar structures throughout the SADC region. The Committee has had a patchy history. Some useful interventions have been made with respect to national genetic resources policy and the ITPGRFA, but a general impression among members is that issues of representation, mandate and scope have hindered its work substantially. Provincial representation in particular, has been inadequate, and a lack of formal status for the committee has led to a rather ad hoc approach. There are now renewed attempts within the Department of Agriculture to reconstitute the body, and to ensure adequate representation from the

provinces. An ongoing debate concerns the location of the committee, and its possible placement within DEAT.⁶⁷ Certainly a reconstituted and reinvigorated committee could provide a much-needed forum for ABS matters to be considered, more especially with the execution of the Biodiversity Act.

In practice, most decision-making about ABS occurs within the organizations issuing permits and transferring genetic material. Table 7.3 describes existing permit arrangements for access to biological resources in South Africa (see also Burgener 2003). Permits for *in situ* material are issued to conduct research or collect biological resources, or both, by the Department of Water Affairs and Forestry, DEAT Marine and Coastal Management, the South African National Parks and provincial conservation and environmental departments and statutory boards. Additionally, a range of institutions host *ex situ* collections and receive ongoing requests for access to material. These include the Department of Agriculture; botanical gardens and herbaria of the National Botanical Institute; museums; universities; Agricultural Research Council; and private seed companies and nurseries.

A lack of integration is evident within the different provincial and national agencies responsible for ABS management in South Africa, and an extremely diverse set of approaches to ABS has evolved in these bodies. In the Western Cape Province, for example, a moratorium currently exists on bioprospecting, both within and outside of protected areas, (although permits have historically been given for collections to take place). In the Northern Cape Province, a prohibition on destructive collecting within protected areas effectively precludes any biological collections from taking place, whether for commercial purposes or not. Within National Parks, proposals are generally assessed on an ad hoc basis, and may be referred to expert groups for opinion. In Gauteng Province, ABS applications are turned down because of a lack of administrative capacity within the department, and insufficient support from national government. Often, uneven understandings and capacities within different conservation agencies lead to inconsistent responses to the same bioprospecting application. Difficulties faced in distinguishing between applications for academic and commercial research further complicate and confuse the situation, although officials are often familiar with applicants and the nature of the research being conducted, making this distinction less fuzzy.

Table 7.3 Current permit arrangements for access to biological resources in South Africa.

Administrative authority	Resources that are mandated for permitting:	Relevant legislation
DEAT, Marine and Coastal Management	All marine resources.	Marine Living Resources Act 18 of 1998
Department of Water Affairs and Forestry	Biological resources located in state forests (note that in some instances this permitting function is devolved to the relevant province).	National Forests Act 84 of 1998
South African National Parks	Biological resources located in national parks.	Protected Areas Act 57 of 2003
National Botanical Institute	Biological resources located in national botanical gardens. Material transfer agreements are required for accessions from the National Botanical Institute (NBI)'s herbaria.	National Forests Act 84 of 1998
National Department of Agriculture	Material transfer agreements required for accessions from the national gene bank.	—
National Department of Agriculture	Issuing of phytosanitary permits for all exports of biological material.	Agricultural Pests Act 36 of 1983
Provincial boards and departments of environment and nature conservation	Permits required for the collection of any biological resources located in provincial nature reserves, as well as for all listed protected species.	Various provincial ordinances and acts

⁶⁷ See, for example, Minutes of the third extraordinary meeting of the national Plant Genetic Resources Committee, 8 October 1999; Minutes of the 7th regular NPGRCOM Meeting, 6 June 2001.

This spectrum of institutions represents the formal front of requests to access genetic resources, but undoubtedly, a host of activities occur outside of any legal framework. In part, this is due to illicit collecting activities, but in the main it results from the lack of adequate legal protection for species outside of protected areas that are not listed as threatened or vulnerable; the vast majority of biological resources in South Africa. To some extent this gap will be addressed by the Biodiversity Act, which requires permits to be obtained for all bioprospecting projects, and for the export of any indigenous biological resource to be used for bioprospecting or any other kind of research. Difficulties remain, however, in distinguishing bioprospecting from other research activities, and this is likely to thwart efforts to effectively control access to South African biodiversity.

The proposed system of ABS administration and decision-making with the implementation of the Biodiversity Act cannot yet be identified precisely, because many provisions of the Act are very general with respect to permitting and procedural arrangements and the role of issuing authorities. Further analysis will thus be required once the Act is promulgated and begins to be implemented.

Access requests and decisions

Permits issued and applications received

Bioprospecting in South Africa is practiced at different levels in different sectors, and through a variety of different approaches. These have varied from general albeit “soft” adherence to CBD norms and the Biodiversity White Paper, the development of government and non-governmental institutional policies to guide projects, contractually binding agreements, and use of the MOU described above.

Historically, bioprospecting in South Africa has involved local intermediaries such as universities, botanical gardens, research institutions, parastatals, gene banks, herbaria, museums and private collectors providing collection and scientific services to companies or foreign intermediaries. Traditional healers and communities have also been approached for their knowledge about the properties of certain organisms, although a substantial part of South Africa’s ethnobotanical knowledge is already recorded in scientific publications and colonial records. More recently, concerted efforts have been made to streamline and coordinate such efforts through the development of national consortia comprising state-based research institutions pooling their expertise and knowledge.

A review of applications to collect biological material in South Africa for bioprospecting and research purposes is summarized in Table 7.4. In many cases, the information is patchy and open to different interpretations, but it does enable an overview of activities over the past 5–10 years on public land and for protected species. Most importantly, it suggests that bioprospecting in South Africa is not nearly as widespread as is popularly believed. Various reasons can be suggested for this trend, including:

- the fact that the vast majority of useful genetic resources have already left the country over the years, and are located in foreign repositories accessible to those wishing to further explore South African genetic resources;
- there is declining interest in natural product development;
- South Africa’s legislative vacuum for ABS has provided a disabling environment for bioprospecting; and
- the development of national consortia has streamlined the process through which permits are granted and reduced the number of individual permits issued.

It is, however, noteworthy that national efforts on bioprospecting have increased over this same period, most especially through the development of consortia. What this implies is that greater collaboration between national institutions is likely to have reduced the number of external agreements made between individual institutions and third parties.

Table 7.4 Applications to collect biological material for bioprospecting and research purposes in South Africa over the past 5–10 years.

Administrative authority	Description of permits issued	Conditions and benefits
DEAT: Marine and Coastal Management	Only one permit issued for bioprospecting (to Rhodes University), but bioprospecting likely takes place using recreational permits or through permit exemptions for research.	–
Department of Water Affairs and Forestry	Since 1986, 93 permits issued for research-related collections in state forests. Only 2 of these have been issued to foreign research institutions, and only 2 are explicitly for bioprospecting purposes (although DWAF itself has not recognized this).	Stated benefits include research reports.
South African National Parks	<i>Information not available at the time of writing</i>	
National Botanical Institute	The NBI comprises 3 herbaria and 8 botanical gardens. The institute both applies for permits to collect outside of botanical gardens, and supplies material to third parties from its <i>ex situ</i> and living collections. Since 1992, more than 33 900 specimens have been sent from the herbaria to both foreign and local institutions. Most specimens have been sent from the national herbarium, which since 1992 has received 200 requests, 77 of them from foreign research institutions. Incomplete records have been collected for botanical gardens, but Lowveld and Pretoria record 8 and 19 requests, respectively, over a number of years, some being for bioprospecting research projects. The vast majority of herbaria requests are for plant systematics research.	A standard MTA accompanies specimens for access to material both in the gardens and herbaria. This aims to prevent commercialization without further agreement. CITES documents and permits are needed for particular species. Stated benefits of providing material include training, co-authorship of papers, species lists, field trip funding, and reciprocal exchanges from other herbaria and gardens. Stated policy is not to make herbaria specimens available for DNA research.
National Department of Agriculture: National Gene Bank	15 requests since 2000, 8 of which are from foreign institutions and virtually all of which are for commercial application. About 20–30 species requested.	A standard MTA is used that excludes commercialization.
Gauteng Province	<i>Information not available at the time of writing</i>	
KwaZulu Natal	671 permits issued from 1996–2003 for the collection of biological material (but not only for research purposes). Only 1 bioprospecting permit issued (to CSIR). Others have been turned down because applicants were foreign.	In terms of organizational policy, requests to collect material in protected areas will only be considered from South African <i>bona fide</i> research institutions. A MOU should accompany such collections, which should be monitored and regulated in terms of current nature conservation legislation. Benefits include species distribution information.
Northwest	<i>Information not available at the time of writing</i>	–
Limpopo	60 research permits (these exclude those issued for use) were issued since 2002. Included are applications for the bioprospecting programme of the Council for Scientific and Industrial Research (CSIR), the anti-malarial consortium, and the Nitrogen Fixation Unit of the Plant Protection Institution of the Agricultural Research Council (ARC).	A standard MOU accompanies the permit.
Western Cape	Since 2002 a moratorium has been placed on all bioprospecting-related research.	A standard MOU accompanies the permit.

Administrative authority	Description of permits issued	Conditions and benefits
Free State	26 applications received and approved over the period 1996–2004 to collect material for research purposes. None are explicitly or obviously for bioprospecting purposes. Seven applicants intended to export the material for research in other countries.	A standard MOU accompanies the permit. Research findings must be made available to the Department. Restrictions on the amounts and species collected pertain to certain permits.
Eastern Cape	<i>Information not available at the time of writing</i>	—
Mpumalanga	<i>Information not available at the time of writing</i>	—
Northern Cape	52 permits issued to collect material for research purposes, including 4–5 permits explicitly for bioprospecting/commercial research and 23 for research based in other countries.	—

Overview of bioprospecting initiatives in South Africa

Key ABS agreements concluded by South African institutions or individuals over the past 10 years are summarized in Table 7.5.

Table 7.5 ABS agreements in South Africa.

Agreement	Resources used	Field of application	Date
CSIR and major South African scientific research institutions and universities	Indigenous medicinal plants	Drug discovery	—
CSIR – Phytopharm	<i>Hoodia</i> and related succulent plant species	Anti-obesity drug development	1997 to present
CSIR – San			
CSIR – Diversa	Microorganisms	?	—
CSIR – traditional healers	TK	Health?	—
SANBI [formerly NBI] – Ball	Indigenous plants	Horticulture	1999–2004
SANBI [formerly NBI] – Kew	Indigenous plants	Conservation through Millennium Seedbank	—
SANBI [formerly NBI] – Kew	South African flowering plants	Conservation/research. Development of a phylogenetic 'tree of life'	—
Medical Research Council in collaboration with other national research institutions	Medicinal plants	Health. Anti-malarial medicines	2001–2003
CSIR – ARC	Indigenous plants	Agriculture: pesticide development	1998
New York Botanical Gardens – Free State University	Indigenous plants	Health	1998–2001
NYBG – Merck		Agriculture	2001–2004
Strathclyde Institute for Drug Research – independent collector	Indigenous plants	Health: drug development	—
Rhodes University – SmithKline Beecham	Marine invertebrates	Health: drug development	mid 1990s
Rhodes University – National Cancer Institute and Coral Reef Research Foundation	Marine invertebrates	Health: anti-cancer drugs	1998–2000
Rhodes University – Scripps Institute of Oceanography	Marine invertebrates	Health: anti-cancer drugs	—

The Council for Scientific and Industrial Research

The Council for Scientific and Industrial Research (CSIR), a South African statutory Board, is undoubtedly the most active and prominent bioprospection player in South Africa.⁶⁸ CSIR Food, Biological and Chemical Technologies (CSIR Bio/Chemtek) has developed a major programme on bioprospecting, which aims to evaluate the pharmaceutical potential of the 18 000–20 000 species of vascular plants native to South Africa.

Key initiatives include:

National bioprospecting consortium, which comprising major scientific research institutions and universities throughout the country. The consortium's focus is the discovery of drugs from indigenous plants, and is considered to "bring together the potential to integrate the strengths of microbiology, chemistry, pharmacology and botany so as to make a considerable and unique contribution to the search for novel drugs in southern Africa and more widely on the African continent". Key partner organizations include the Medical Research Council, National Botanical Institute and Agricultural Research Council. Funding has been obtained from the National Research Foundation's Innovation Fund for a major project focused on anti-malarial drugs (discussed later).

Anti-obesity drug development. The appetite suppressant drug (dubbed "P57") is derived from a species of *Hoodia*, a succulent plant indigenous to southern Africa and long used by the San to assuage hunger and thirst (Wynberg 2004). The appetite suppressant is considered to have the potential to become the first blockbuster drug to be derived from an African plant and is to be commercialized into a prescription medicine with an estimated market potential of more than US\$ 6 billion. The active components of the plant have been patented by the CSIR who, in 1997, signed a licensing agreement with Phytopharm plc, a small UK research-based pharmaceutical company. Phytopharm in turn sold the rights to an exclusive global licence for P57 to Pfizer, a US pharmaceutical company better equipped to take promising leads through the development phase (but that has recently withdrawn from the agreement). At the time, no arrangement was in place to benefit the San for their TK, but through lobbying from NGOs and San-affiliated organizations, the case became a high-profile story in the media. In 2003, an agreement was reached between CSIR and San on a financial benefit-sharing agreement, which – if the product is successful – will see the San receiving 6% of all royalties received by CSIR, and 8% of the CSIR's milestone income received when certain targets are reached. Money will be paid into a Trust set up by CSIR and the South African San Council to uplift the standard of living and well-being of the San peoples of Southern Africa. The initiative has received wide acclaim although there are concerns with respect to the limited benefits received by the San, and the restriction on their use of knowledge of *Hoodia* in any other commercial application. In 2004, the consumer giant Unilever plc was granted an exclusive global licence by Phytopharm for use of *Hoodia* species in existing food brands.

Diversa. CSIR and the US-based Diversa Corporation signed an agreement giving Diversa the rights to obtain microbial samples from South Africa and to commercialize products. In exchange, Diversa will support the ongoing bioprospecting activities of CSIR and its

⁶⁸ The CSIR represents one of the largest research organizations in Africa, accounting for about 10% of the entire African research and development budget. It operates under the following mandate: "In the national interest, the CSIR, through directed and multi-disciplinary research and technological innovation, should foster industrial and scientific development, either by itself, or in partnership with public and private sector institutions, to contribute to the improvement of the quality of life of the people of South Africa". About 40% of its annual budget is derived from the state.

collaborators and pay royalties on revenues from any products developed from samples provided.

Traditional healers. Ten traditional healers signed an agreement to collect TK for CSIR. The benefits from the commercial use of the knowledge are paid into a trust administered by the healers.

Animal health. A three-year project with an undisclosed partner, which is focused on animal health.

Mosquito repellent. A mosquito repellent is developed based on local knowledge and plant species. A South African patent has been granted for the active constituents of the plant and investigations are underway with respect to its cultivation.

The South African National Biodiversity Institute

The South African Biodiversity Institute (SANBI) is a public institution that aims to 'to promote the sustainable use, conservation, appreciation and enjoyment of the exceptionally rich biodiversity of South Africa, for the benefit of all people' and also to promote the economic use and potential of indigenous plants. It does this *inter alia* through managing the various botanical gardens and herbaria in South Africa, conducting environmental education and developing databases on Southern Africa flora. The organization employs over 500 people and manages an operating budget of some US\$ 14 million (2005/2006), 81% of which it receives from Parliament. A senior manager within the institute is the central contact point for all ABS issues, and this has assisted in streamlining ABS policies and practices. SANBI is involved in bioprospecting both as player and partner. It is a decision-making body responsible for *ex situ* and garden collections, represents the government in several policy forums, and is involved in ABS-related initiatives"

SANBI and Ball Horticulture.⁶⁹ In 1999, the then National Botanical Institute (NBI) entered into a Research and Licensing Agreement with the Chicago-based Ball Horticulture, one of the world's largest horticultural companies. The five-year agreement, which is the first North-South bioprospecting agreement in the horti- and flori-culture sector, mandates SANBI to select South African plants of horticultural interest to Ball from its living collections and the wild. Ball will patent any selected or hybridized varieties of these plants, and SANBI will receive a cut of profits for 20 years following the plant's introduction to the market. Profits generated by the agreement will be placed in a specific account administered by the SANBI Board, to be used for capacity building in botany and horticulture (although this will become redundant with the establishment of a Bioprospecting Fund by the Biodiversity Act).

Other benefits include staff training and the building of greenhouse facilities, where plants will be propagated before being sent to North America. The first plant to be successfully commercialized as part of the agreement is a hybrid of two *Plectranthus* species, developed by SANBI and thus securing a 10% royalty for the Institute. 'Mono Lavender', the resulting cultivar, is now commercially available throughout Europe, the USA, Japan and South Africa. Plant Breeders' Rights have been granted worldwide for the variety, and application has also been made in South Africa. Such application has been made by Ball on behalf of SANBI. The agreement, due for renewal and renegotiation in 2004, represents a significant effort by South Africa to control the use of indigenous genetic resources in the global horticultural trade, but has met with heated controversy from stakeholders who

⁶⁹ A comprehensive review of the agreement is provided by Wynberg (2003). See also Henne and Fakir (1999) and Glazewski et al. (2001).

perceive it to be too wide in scope, weak in benefit-sharing arrangements and technology transfer, and inadequate in terms of job creation and local economic development.

The Millennium Seedbank. SANBI is the South African partner in the Millennium Seedbank Project of the Royal Botanic Gardens, Kew. This is an international collaborative plant conservation initiative, which aims to safeguard 24 000 plant species from around the globe against extinction. An emphasis is placed on dryland plant species and on strengthening in-country capacity for seed banking. The collection of threatened and endemic species forms a major part of the project in South Africa. Commercialization of the seed is not intended, a legally binding ABS agreement governs the relationship between Kew and SANBI and requires a separate commercial agreement to be developed in the event of commercial interest.

DNA banking. In another collaboration with Kew, SANBI has set up a DNA bank to archive the genetic material from at least one species of all 2200 South African flowering plant genera. The objective is to allow researchers to have access to plant DNA extracts and to produce a phylogenetic 'tree of life' of South African plant genera. An MTA restricts commercial use of the material supplied.

Medical Research Council

The Medical Research Council, which facilitates and coordinates health and medical research,⁷⁰ is strongly involved in bioprospecting through drug research and development.

Key projects include:

Anti-malarial medicines from the medicinal plants of Southern Africa project.⁷¹ A project on anti-malarial medicines from medicinal plants has recently been completed by a consortium comprising the South African Medical Research Council (MRC) (Lead agency), University of Cape Town (UCT), CSIR, NBI, University of Western Cape and University of Pretoria (UP). The project was funded by the Department of Arts, Culture, Science and Technology (DACST) through the Innovation Fund, and had a budget of R 6.7 million extending over 3 years (2001–2003). The consortium has a database containing 2300 records of 700 plants claimed to be used in the treatment or prevention of malaria.

The aim of the project was to develop new medicines, based on indigenous plants and knowledge for the treatment of malaria. The project was expected to lead to the establishment of new agro-processing businesses for the supply of extracted plant material for use in new anti-malarial drugs. A focus was placed on two plants shown to have potential to combat chloroquine resistance of certain malaria strains. The project is intended to create multidisciplinary scientific capability to derive anti-malarial medicines; create jobs through cultivation and agro-processing; develop a technology platform for South Africa, comprising all the elements of the "value chain" for drug discovery; and create economic benefits for South Africa through product innovation and royalty earnings. Any financial benefits generated as a result of the project are to be shared equally as 50% by partners of the consortium, and the remaining 50% deposited into a Trust Fund to share with "stakeholders" that have contributed to the project.

A national research and development platform for novel drug development from indigenous medicinal plants.⁷² This 3-year project includes the Agricultural Research Council (post harvest), CSIR (Bio/Chemtek), MRC (Business Development; Diabetes

⁷⁰ MRC Act 58 of 1991.

⁷¹ See also www.sahealthinfo.org

⁷² For further information see www.sahealthinfo.org

Management, IKS; TB Research; Malaria Research); National Botanical Institute (Ethnobotany, Research and Education, National Herbarium); Rand Afrikaans University (Botany; Chemistry); University of Cape Town (Chemistry; Immunology; Medical Microbiology; Pharmacology; Surgery); University of the North (Pharmacology); University of Natal, Durban (Chemistry); and University of Pretoria (Biochemistry, Botany).

The project aims to develop: new medicines, effective against tuberculosis, malaria, diabetes mellitus and for immune modulation; and tonics from indigenous southern African plants, based on local knowledge. The project is expected to discover novel drugs and tonics ready for early clinical studies, patenting and further development in conjunction with an industrial partner, World Health Organization or other collaborative arrangements. An important feature of the project is its consortium approach, based exclusively on South African institutions working on Southern African indigenous plants. Benefit-sharing arrangements are at this stage unclear.

Agricultural Research Council

The Agricultural Research Council⁷³ (ARC) is a statutory body, formed under the Agricultural Research Act of 1990 with a mandate to conduct and undertake research, development and technology transfer. The ARC manages several *ex situ* collections of plant material within the country and is engaged actively as a partner in various bioprospecting initiatives.

One of the ARC's key projects is a focused effort by its Plant Protection Research Institute (PPRI) to identify novel pesticides from indigenous plants. In terms of a 1998 Agreement with the CSIR, the ARC tests CSIR plant extracts for potential activity against major agricultural insect pests and fungal and bacterial plant pathogens. The project forms part of a broader consortium led by the CSIR and is also linked to laboratories at Rothamsted in the United Kingdom. Through laboratory screening procedures the project has yielded 16 "hits" showing insecticidal activity, 12 hits with anti-bacterial activity and 30 hits with anti-fungal activity. A selected number of these hits are being investigated further by CSIR using fractionation procedures. The project has also established three bioassay screens of international standards, capable of detecting specific pesticidal activity. The establishment of a screen for detecting herbicidal activities in extracts is under consideration. The stated aim of the project is for the ARC-PPRI to generate jointly, with CSIR, financial gain through patenting, out-licensing, and royalties of any pesticidal compounds discovered.

The New York Botanical Garden and Free State University⁷⁴

This project involves collaboration between the New York Botanical Garden (NYBG) and the University of the Free State (UFS) in Bloemfontein, initiated through Letters of Agreement, signed in 1998 and renewed in 2001 for a further 3 years. Through these agreements, South African plant material is collected by the NYBG, in collaboration with: the Department of Botany at the UFS, which provides botanical support and expertise to the project; and the Department of Agronomy at the UFS, which tests phytochemical compounds for potential agronomic application and supplies extracts to Merck Research Laboratories in the USA.

The goals of the research programme, as articulated in the Letters of Agreement, are:

"establishment of research on plant biodiversity within the Republic of South Africa, through linkages to modern phytochemistry, as a means of promoting its conservation and use;

⁷³ www.arc.org.za

⁷⁴ For a comprehensive review of this initiative, see Wynberg (2003).

“discovery of new therapeutic compounds that have potential application to modern natural products’ chemistry, as well as veterinary and agricultural practices by a plant collection, laboratory extraction, and screening programme;

“strengthening of conservation efforts through botany, horticulture, public education programmes, and the search for alternative agronomic crops at UFS through infrastructure development; and

“establishment of a collaborative inter-institutional relationship for research in basic, applied, and conservation biology, as well as phytochemistry, between collaborating institutions”.⁷⁵

These goals form part of a long-term Global Systematic Phytochemical Survey, initiated by NYBG in 1986 in an endeavour to systematically collect representatives of every vascular plant family in the world. The main intention is to conduct phytochemical screening to discover where biological activity occurs in the plant kingdom, and to develop novel compounds that show promise for new pharmaceutical and agricultural and veterinary products. No information is obtained from traditional healers, *sangomas*, or other holders of TK, although plants collected may well be documented as having particular applications based on TK and use. Primary clients of NYBG include the National Cancer Institute, Pfizer, and Merck. Merck is the only client receiving South African material. To date, some 700–750 South African genera have been collected by NYBG, with 80–100 of these genera representing introduced exotics.⁷⁶ Thus far, no commercial applications have been developed from either the South African material or species occurring elsewhere in the world.⁷⁷ Three species are, however, considered to show good promise for agricultural application and commercial rights for their development will remain in South Africa.⁷⁸

In terms of benefits, the project has led to significant spin-offs for the UFS that would not have been realized without external support, especially in light of financial difficulties faced by the university. The NYBG has benefited by dint of a full research grant from Merck to support its global phytochemical survey and the possibility of deriving royalties from the development of commercial products. Despite these benefits, those critical of the project point to its lack of substantial value-adding within South Africa – especially with regard to commercial research and development, its weak provisions with regard to maintaining IPRs in South Africa, and the difficulties of holding NYBG accountable when benefits are possibly realized in ten or twenty years from now.

Strathclyde Institute for Drug Research and an independent plant collector: Random screening of South African plants for drug development

This project started in 1999 and involves an agreement between Strathclyde Institute for Drug Research (SIDR), Glasgow, UK, and an independent plant collector. Up to 300 South African species have been supplied to SIDR as dried plant material, with SIDR undertaking random screening, and identifying early stage commercial opportunities for drug development. The collector is paid a ‘handling charge’ per sample as well as 60% of any fees obtained from third parties that access extracts for evaluation purposes. An ‘Ethnobotany Fund’ has been established by the collector at the University of Stellenbosch in anticipation of successful commercialization, but thus far no monies have been deposited into the fund.

In Glasgow, samples are maintained in a library of natural products held by SIDR, purported to be one of the most diverse collections commercially available, and including

⁷⁵ Letter of Agreement between Department of Agronomy, UFS and NYBG, 31 January 2003; Letter of Agreement between Department of Botany and Genetics, UFS and NYBG, 31 January 2003.

⁷⁶ R. Brand, NYBG, pers. comm., December 2002.

⁷⁷ Ibid.

⁷⁸ Letter to R. Wynberg from Professor J. Venter, Dr A. Venter, Professor S. Pretorius and R. Brand, on behalf of the University of the Free State, November 2002.

examples of more than 70% of the plant families of the world. Access to SIDR's natural product library is available under licence to industry, and agreed quantities of extracts are provided with exclusivity for an agreed period, with guaranteed taxonomic identification and re-supply. South African material has been included in two industry contracts with the SIDR, but little interest has been expressed to date in this material.⁷⁹

A recent analysis of the case (Wynberg 2003) points to the pitfalls of operating in a legal vacuum, evidenced by the extremely weak benefit-sharing provisions of the agreement, and lack of commitment to add value to resources for national benefit.

Department of Biochemistry and Microbiology, Rhodes University: Fungal bioprospecting

This project involves the isolation of a laccase enzyme with industrial application from a fungus discovered in the Eastern Cape. Applications include the detoxification of industrial effluent from paper, pulp and petrochemical industries, and use as a tool for medical diagnostics and bioremediation agent to clean up herbicides, pesticides and certain explosives in soil. It is also used as a cleaning agent for certain water purification systems, as a catalyst for the manufacture of anti-cancer drugs, and an ingredient in cosmetics. It is considered to be the first fungus of its kind to be isolated internationally.⁸⁰

Rhodes University, Department of Chemistry: Marine bioprospecting

The Department of Chemistry at Rhodes University is actively involved in natural product development using South African marine organisms. Past projects have entailed a collaboration between Rhodes University and SmithKline Beecham in the mid-1990s, and from 1998-2000, between Rhodes University, the USA-based National Cancer Institute, and the Coral Reef Research Foundation from Micronesia (see also Wynberg 2002). Neither of these projects led to commercial developments, but both have contributed substantially to the building of South African capacity in marine invertebrate taxonomy and natural products chemistry, and the purchase of equipment.⁸¹ The Department is currently collaborating with the Scripps Institute of Oceanography, looking for new anti-cancer drugs from South African marine organisms. It is sponsored by National Institutes of Health. No commercial developments have arisen from this programme, but it has yielded benefits through student training. An important library of extracts made from South African marine invertebrates is housed at Rhodes University. It was obtained from SmithKline Beecham following the closure of its natural products drug programme and from ongoing projects in this field.

Main legal issues

Current practices, combined with the legal and institutional situation, as analyzed earlier, suggest a number of critical issues that require resolution and which cause practical problems in implementation of the laws. Some of these are legal, and many relate to issues of capacity and understanding.

The absence of legal and administrative mechanisms to control access to South Africa's genetic resources, and to set conditions for benefit-sharing, has been a key constraint in achieving more meaningful benefit-sharing arrangements in South Africa. New legislation to regulate ABS will change this significantly, but may be hindered in implementation by the lack of a central focal point and "secretariat" for bioprospecting and unclear permit and procedural arrangements.

⁷⁹ Alan Harvey, SIDR Director, pers. comm., December 2001.

⁸⁰ <http://www.scienceinafrica.co.za/2004/january/fungus.htm>

⁸¹ E-mail communication from M. Davies-Coleman, 9 March 2004.

As described earlier, the national government has played a near-absent role in developing ABS agreements, both in terms of its lack of administrative support and role as a central focal point and clearing house, and through its lack of leadership in providing support, advice and facilitation. Generally, complex and difficult negotiations have been left to develop in a policy and administrative vacuum, at the whim of individual scientists who have had neither the skill nor expertise required to develop appropriate agreements. Largely as a result of this lack of national oversight, many agreements fall short of including requirements to satisfy national social, economic and environmental imperatives. At the provincial level, different approaches are taken by different provinces, which have uneven understandings and capacity to deal with the issue, leading to inconsistent responses, often to the same bioprospecting application.

The scope of access, and lack of clarity on definitional and ownership issues, are likely to be hurdles in implementing ABS laws. The grey area between research and commercial development is not well recognized by ABS laws and, other than for export purpose, research is currently excluded from legal purview. This omission will effectively exclude many bioprospecting projects from stipulated permit requirements, because of the difficulties of distinguishing between academic and commercial research. The broad definition used for bioprospecting and indigenous biological resources within the newly promulgated Biodiversity Act will require further consideration and scrutiny with respect to implementation.

ABS regulation in communally and privately owned land is likely to be extremely difficult to implement and monitor. A noticeable trend in South Africa is that bioprospectors seem to be intentionally avoiding community-owned areas and are instead opting to collect on state-owned land (often protected areas) or privately held farms, where PIC is a simple procedure that does not require lengthy and complex negotiations with a community. The same applies for TK about South African plants, which is already publicly available. The PIC requirement articulated in the Biodiversity Act, although crucial, may act as a further obstacle for investment in communal areas.

Provisions in the Biodiversity Act, which require “benefit-sharing agreements” to be developed and approved by the Minister with all the providers of resources and knowledge are confusing. They fail to recognize the different steps and stakeholders in the process of developing a benefit-sharing agreement, and the fact that benefit-sharing agreements are typically only developed once research and development is further advanced. Clarity and guidance will be needed for applicants and permit issuing authorities with respect to the practical implementation of these provisions.

A requirement in the Biodiversity Act for Ministerial approval for all Material Transfer Agreements may lead to lengthy delays, and may well be unnecessary. MTAs simply represent an agreement between parties to transfer specimens and to not commercialize them without first developing a benefit-sharing agreement.

Historically, little attention has been paid to the need to obtain PIC from holders of TK. This is best illustrated through the case of the San, who only recently learned about the patenting of their knowledge about *Hoodia* by the CSIR, for use in an anti-obesity drug. The San have now retrospectively been included in a benefit-sharing agreement with the CSIR, but many questions remain unresolved: who qualifies as the rightful community or group from whom consent should be obtained? Can knowledge be attributed to a single group or individual? Is the privatization of TK through IPRs not contrary to the belief of many communities that such knowledge is collectively held, for the benefit of the broader community? What happens – as in the case of the San – when consent is only obtained after the fact? Communities clearly require legal and strategic assistance in dealing with these issues, combined with active and ongoing vigilance of patent applications for ‘prior art’, or knowledge already recorded. A supportive legislative environment is also critical –

especially given the difficulties and inappropriateness of using existing intellectual property systems to protect community and indigenous rights.

Several bioprospecting initiatives in South Africa have floundered, because of the limited attention they have paid to involving different role-players, and the often confidential nature of agreements. Bioprospecting, more than many other biodiversity issues, raises charged emotions, because of its historical tendency to over-ride equity and social justice considerations. However, no provision is made in the Biodiversity Act for stakeholder involvement in decision-making and this, combined with a discretionary clause for the Minister to intervene to ensure fair and equitable benefit-sharing, suggests that those actively engaged in bioprospecting need to take extra care in ensuring that the interests of all stakeholders are accommodated when negotiating agreements. Institutional arrangements for ABS decision-making under the Biodiversity Act are as yet unclear.

Access to PGRFA, mostly in *ex situ* collections, is currently fragmented across a number of institutions, and in some instances is uncontrolled. Consideration may need to be given to the establishment of an issuing authority for PGRFA and *ex situ* collections.

A number of crucial legal gaps remain. First, despite longstanding initiatives to develop legislation to protect and promote indigenous knowledge, these have not come to fruition and there is currently no legal protection for holders of TK. Second, farmers' rights remain unrecognized, and there is little consensus as to how this matter should be legally resolved. South Africa, which is one of the few African countries to have a plant variety protection regime in place, is a party to the 1978 UPOV Act and is considering ratification of the 1991 version. This is in keeping with the country's history of industrial agriculture, and the presence of a strong commercial breeding sector. However, little supportive legislation currently exists to broaden the system to include farmers and communities that have traditionally bred and developed crops and that have in some instances, provided knowledge and resources to commercial breeders. Third, South Africa has well-developed patent laws but they require review to ensure consideration of ABS and TK issues. Moreover, a number of issues relating to the interface between TRIPS and the CBD have not yet been resolved at national level. In addition to TK protection, these include the disclosure of origin for patent applications; and approaches towards the patenting of life. Aligning procedures and definitions between different authorities and laws provides an enormous challenge to authorities and legislators.

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8. Uganda

Robert J. Lewis-Lettington and Peter G. Munyi

Introduction

This paper does not seek to provide a detailed examination of all aspects of the legal framework, and experiences under that framework, affecting access to genetic resources in Uganda. This is partly because this task has been undertaken elsewhere,⁸² and partly because the paper is intended to highlight a series of key issues that have been raised in the context of the IPGRI project, "Access and plant genetic resources for food and agriculture: Exploring options to implement the International Treaty on Plant Genetic Resources for Food and Agriculture and Article 15.2 of the Convention on Biological Diversity." Accordingly, the paper first examines the Ugandan understanding of the term "genetic resources", and the related question of the scope of application of its legal regime. It then proceeds to consider the legal framework providing for the ownership of genetic resources and the subsequent question of rights to control access to those genetic resources. The third major element of the paper describes, in detail, the administrative process for the approval of requests for access to genetic resources and, finally, there is an overview discussion of the evolving nature of access activities and regulation in Uganda.

The definition of genetic resources in Uganda

The term "genetic resources" is defined in the two Ugandan legal instruments that are central to the country's access to genetic resources regime:

1. the National Environment Statute (1995),⁸³ Uganda's framework environmental law (hereinafter "Statute"); and,
2. the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2002 (hereinafter "ABS Regulations")⁸⁴.

The definitions of the term provided for in each instrument are simply verbatim adoptions of the corresponding text from the Convention on Biological Diversity (CBD) that only provide limited substantive meaning.⁸⁵ To develop the definition of "genetic resources", however limited, of the legislatively intended substantive definition in the Ugandan law, one also needs to consider the regulations regarding scope (Article 4).

The Statute adopts, in Section 2, the CBD's definition of genetic resources verbatim, but does not include the accompanying definition of genetic material on which the CBD definition depends. However, the ABS Regulations, which are intended to implement the provisions of the Statute relating to access to genetic resources include, in Section 2, the CBD definitions of both genetic resources and genetic material. However, they do not provide any further clarification of these definitions. As is discussed in more depth by Nnadozie et al

⁸² For a general discussion of access to genetic resources in Uganda, see Tumushabe G and Mpeirwe A. 2003. Access to genetic resources in Uganda. In: Nnadozie K, Lettington R, Bruch C and King S, editors. *African Perspectives on Genetic Resources: A handbook on laws, policies and institutions*. African Union-STRC/ELI/SEAPRI. pp. 247-259.

⁸³ The National Environment Statute (1995) is available online at <<http://www.nemaug.org>>. Last checked October 2003.

⁸⁴ The draft regulations were approved by the Cabinet in February 2004 and subsequently formally gazetted, meaning that they are now in force. Personal communication to the authors by Dr Charles Mugoya, Deputy Executive Secretary, UNCST.

⁸⁵ In the sense that the CBD definition of "genetic resources" depends upon the definition of the related term "genetic material". This is discussed in more detail in the following paragraphs.

(2003)⁸⁶, a simple adoption of the CBD definitions does not provide a substantive definition of the term genetic resources but leaves the definition to national discretion. Hence, the Ugandan definition simply indicates that one is dealing with a legal-political construct rather than a physical interpretation, without actually specifying what that construct is.

The Uganda authorities view the question of definitions as one that is adequately addressed by the draft regulations and the nature of particular views tends to follow the formal role of individual institutions. The National Environmental Management Authority (NEMA), as the key policy-making institution regarding the regulations, sees it in terms of implementation of the CBD and is thus satisfied that the regulations comply with Article 3 of the CBD,⁸⁷ which is clearly correct on a technical level. The Uganda National Council for Science and Technology (UNCST), as the primary implementing agency, focuses more on the substance of the definitions and believes that the definition is sufficiently precise given that the intention is to address all “biological substances which contain genes or biochemicals of interest” and derivatives as broadly as possible.⁸⁸ Despite this general level of satisfaction with the definition of “genetic resources”, UNCST does see the question as closely tied to the scope of the regulations.

Scope

Section 4 of the Ugandan regulations, Application of these Regulations, provides for the general scope of the regulations with some elements of a substantive definition and, at a minimum, allows for some specific understanding of “genetic resources” in the context of the Ugandan regulations. Section 4 constitutes what is more commonly known as the “scope of application” element of the ABS regulations and is divided into 3 subsections, 2 of which are of significant interest for the purposes of discussion here. Subsection 4.1 refers to what is considered as within the ambit of the regulations:

“...genetic resources or parts thereof, whether naturally occurring or naturalized including those bred for or intended for commercial purposes within the territory of Uganda or for export, their derivative products and their intangible components, whether in *in situ* or *ex situ* conditions, and includes local knowledge, technology, innovations, farming practices and traditional lifestyles.”

This does not address the underlying ambiguity regarding the definition of “genetic resources”. However, it suggests an intention to include all biological organisms found within Ugandan jurisdiction. The reference to “intangible components” is also clearly intended to bring in related knowledge of genetic resources, particularly TK, within the scope of the regulations. This latter point is reinforced by the reference to “local knowledge, technology, innovations, farming practices and traditional lifestyles”. A final point worthy of note is the reference to “derivative products”, which is separately defined in Section 2:

“‘Derivative product’ means unimproved or unmodified biologically active chemical compound(s) associated with targeted biological material and formed by the metabolic processes of the organs, but are yet to be extracted, modified and used in a technological application. They include molecules, combinations or mixtures of natural molecules including raw extracts of living or dead organisms and soil matter. Without prejudice to this meaning, derivative products shall also include deoxyribonucleic acid (DNA), ribonucleic acid (RNA) or chemical compounds, which are

⁸⁶ Nnadozie, K., et al. (Eds.), Chapter 2: The Significance of Genetic Resources in Africa at 9 to 11 in ‘African Perspectives on Genetic Resources: A Handbook on Laws, Policies and Institutions’ at 9 – 24 (African Union, 2003).

⁸⁷ Personal communication to Peter G. Munyi by Robert Wabunoha, Senior Legal Counsel NEMA (19 March 2004).

⁸⁸ Personal communications to Peter G. Munyi by Dr. Charles Mugoya, Deputy Executive Secretary UNCST (16th March 2004) and Dr. Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

modified, created or synthesised from genetic material originally obtained in accordance with these regulations.”

There are two central elements to this definition of derivative product. The first includes any naturally occurring elements of the organism in question that have not been modified or given technological application.⁸⁹ Raw extracts are included in this element, suggesting that Uganda does not consider simple extraction as an inventive step for the purposes of IPRs. The second element of the definition partially clarifies the first by stressing that DNA, RNA and chemical compounds, whether extracted, modified, synthesized or created from an organism, are considered as derivative products. This clarification is potentially very broad as it could encompass products that are considerably downstream in the technological process from the original organism. In general terms, the Ugandan use of “derivative product” follows an aggressive interpretation of the African Group position in forums such as WIPO and the TRIPS Council.

Subsection 4.2 narrows down the catch-all approach of Subsection 4.1 by providing for exclusions to the scope of the regulations. All of the exclusions provided for in Subsection 4.2 fit the pattern of legal-political constructs that relate to the perception and use of a resource rather than its physical nature. Subsection 4.2(a) provides for the exclusion of internal local community⁹⁰ use of genetic resources from the ambit of the regulations. Subsection 4.2(b) is also a legal-political exclusion focusing on agricultural and other extractive production, such as timber: the exchange of genetic resources, their derivative products, or the intangible components associated with them, which are certified to be purely for food or other consumptive purposes as prescribed by the relevant laws.

The exclusion provided for in Subsection 4.2(b) is more problematic than that in 4.2(a). First, it highlights the complexity resulting from not having a complete definition in Section 2 by requiring repeat references to derivative products and intangible components. Second, while food is a relatively straightforward concept,⁹¹ other purely consumptive purposes are more ambiguous. The intention is to refer to timber extraction, cut flowers and similar industries,⁹² but this is not automatically apparent. A third complication arises from the requirement for certification, as it is not entirely clear what form of certification is required. A large proportion of agricultural and extractive production does not require formal certification of the purpose of the production. The question arises as to whether a producer can self-certify by not applying for authorization for access to genetic resources that are purely for food or other consumptive purposes. This implies that the definition of genetic resources might not be entirely in the hands of the legislature and the competent authority,

⁸⁹ The fact that the text reads “extracted, modified *and* used in a technological application” (emphasis added), rather than “or used” could be interpreted to mean that all three of these criteria must be fulfilled, rather than any one or two of them, before one moves beyond the scope of a derivative product. This interpretation is generally supported by the later language clearly stating that raw extracts, DNA and RNA are all derivative products.

⁹⁰ “Local community” is defined in Section 2 as “an indigenous community of Uganda as provided for in the Third Schedule to the Constitution, or any clan or subclan of any such indigenous community communally occupying, using or managing land in which the genetic resource is found”, thereby avoiding some of the potential ambiguities that may arise with the use of this term.

⁹¹ The increasing importance of the market for nutraceuticals, or food supplements, could complicate this.

⁹² One of the authors was a consultant involved with the preparation of the first draft of the Ugandan regulations in 1999. Thus, this statement is based on the author’s understanding of relevant legislative history.

but may also be influenced by the activities of individuals. Finally, which are the “relevant laws”?

As it relates to the question of the definition of genetic resources, Subsection 4.2(c) is relatively straightforward. It simply provides that genetic resources not having their immediate origin in Uganda are not subject to the regulations.

Subsection 4.2(d) excludes genetic resources derived from plant breeders as defined under the relevant laws relating to plant breeding and plant variety.⁹³ This exclusion has potentially broad application in the agricultural sector and raises a number of questions. The fundamental question is whether it refers to all genetic resources derived from plant breeders (“plant breeders” being the term to be sought under relevant laws) or only to genetic resources that may fall within the ambit of these relevant laws?⁹⁴ The distinction is important in that the volume of genetic resources that a plant breeder uses is huge, as opposed to that which is ultimately subject to plant breeding or plant variety protection regulation. Whichever of these two interpretations is correct, it clearly intends to exclude a major aspect of the agricultural sector and focus the regulations on non-agricultural uses. In this sense, it complements Subsection 4.2(b), excluding food and consumptive purposes, by also excluding the research elements that underlie food products.⁹⁵ However, either of the interpretations implies restrictions that raise questions on the rationale. If the exclusion relates to plant breeders, why are they singled out as a group for special treatment? If the exclusion relates to genetic resources that fall within the ambit of laws relevant to plant breeding and plant variety protection, why does it not also include genetic resources that are useful for plant breeding but which are not eligible for, or have voluntarily not been subjected, to monopoly protections under these laws? This also leads to the related question of why the exclusion only addresses genetic resources derived from plant breeders and does not consider those that plant breeders might access from non-plant breeders or the wild?

Subsection 4.2(d) also raises other questions, on the precise meaning of “derived from plant breeders”, as there is no indication of the proximity of relationship required to fall within the scope of this phrase. However, the final point to be noted here is that this exclusion seems to address the concerns that led to the development and adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).⁹⁶ If this is the case and given that Uganda has already acceded to the Treaty, a simpler approach might be that advocated by the Conference of the Parties to the CBD: advocating that the

⁹³ It is assumed that “plant variety” is a typographical error that should read either “plant variety protection” or “plant varieties”.

⁹⁴ In the opinion of the authors, the simplest interpretation would suggest that the intention is the former (to refer to all genetic resources derived from plant breeders), as the alternative would create ambiguities relating to the nature of genetic resources under other relevant legislation. However, the fact that this interpretation would create an enormous exception in a critical sector (agriculture) that is restricted to a limited range of actors within that sector (formally recognized plant breeders) makes this simple interpretation difficult to accept. In addition, one must consider that this interpretation would potentially create an even larger exception in that it would not require that the genetic resources derived from a plant breeder relate to that breeder’s plant breeding activities: they could be medicinal plants or industrially useful microorganisms. The interpretation excluding genetic resources that are the subject of relevant laws might be more complex in terms of understanding genetic resources in the context of those laws but would create a far more limited and, in the opinion of the authors, rational, exclusion.

⁹⁵ It should be noted that those developing varieties of flowers, ornamental plants and, in some cases, medicinal plants can be legally considered to be plant breeders and thus potentially able to make use of this exclusion.

⁹⁶ Uganda acceded to the ITPGRFA on 25 March 2003 and the Treaty entered into force on 30 June 2004. See www.fao.org/cgrfa.

subject matter of the ITPGRFA be specifically excluded from the scope of national ABS regulations.

Subsection 4.2(e) provides for the exclusion of human genetic resources from the scope of the regulations. This is not an uncommon exclusion with many countries holding that it would be immoral, or at the very least unethical, not to provide for it. Several points should be noted in this regard. First, excluding human genetic resources from the scope of ABS regimes does not ban such activities; they are not subject to ABS regulation and thus may be freely conducted subject to any other legal provisions that may be in force. Second, if the aim is to ban activities involving human genetic resources then the ABS regulations or another relevant legal instrument, should explicitly state that such activities are prohibited. Third, an outright ban on research involving human genetic resources should be carefully considered. A substantial amount of valuable advanced medical research involves human genetic resources, such as blood or tissue samples. A good example of this is the International Acquired Immuno-deficiency Syndrome (AIDS) Vaccine Initiative (IAVI), which supports several initiatives based on human blood samples. The problem with research involving human genetic resources is often not the actual research involving such material, but rather, the way such research is conducted. This would seem to call for stricter scrutiny in regulation rather than having no regulation at all.

Subsection 4.2(f) is another apparently broad exclusion focusing on national research activities:

“approved research activities intended for educational purposes within recognized Ugandan institutions only, which do not lead to accessing genetic resources for commercial purposes or export to other countries ...”

There are several elements of this exclusion that significantly narrow its scope. Firstly, it is restricted to activities intended for educational purposes. The exact meaning of this restriction depends upon the interpretation of “educational purposes”. Considerable research is undertaken by faculties in modern universities, such as Makerere, that is in addition, and not integral, to the educational programmes. However, this research is clearly undertaken in the context of an educational establishment. To compound the problem many tertiary educational institutions are under ever-increasing pressure to generate revenue from their research, meaning that programmes often do have an ultimately commercial objective. Perhaps more problematic is the situation of national research institutions, such as the National Agricultural Research Organization (NARO) or the National Chemotherapeutics Laboratory, which are not educational establishments *per se* but often host and train graduate researchers.

This approach also raises problems in terms of assessing what activities are intended for commercial or export purposes. These options often arise relatively late in the process of biological research and thus may not be apparent at the point of access to the genetic resources. The final point to note about Subsection 4.2(f) are the qualifying terms “approved” and “recognized”. These are clearly intended to restrict the exclusion to a limited range of institutions, but what is not clear is approved or recognized by whom and for what?

The precise scope of the ABS regulations is, to some degree, the subject of an ongoing discourse within, and among, the Ugandan authorities. The central focus of this discourse is the general field of food and agriculture. UNCST views the ABS regulations as somewhat compatible with Uganda’s obligations under the ITPGR,⁹⁷ but recognizes that the regulations

⁹⁷ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

were developed with only the environmental concerns of the CBD in mind⁹⁸ and maintains the official position that they do not consider the provisions of the ITPGRFA.⁹⁹ The view that the ABS regulations do not contain adequate provisions specifically addressing genetic resources for food and agriculture appears to be widely held.¹⁰⁰ As a result, UNCST tends to closely consult NARO and the Entebbe Botanical Gardens on all matters related to genetic resources for food and agriculture.¹⁰¹ A further result of the perceived lacunae regarding genetic resources for food and agriculture is an initiative by NARO, through the Entebbe Botanical Gardens, to develop draft regulations specifically implementing the ITPGR and in particular its provisions regarding farmers' rights and uniform material transfer agreements.¹⁰² Rather than being overlapping, or contradictory initiatives, it is expected that the draft ITPGR implementing regulations will provide a basis for the amendment of the ABS regulations.¹⁰³ Similar approaches can be expected for the harmonization of the ABS regulations with existing sectoral policies, such as the guidelines on germplasm collection and collection of plants with chemotherapeutic qualities, as these are often also implemented by UNCST.¹⁰⁴

Definition and scope: conclusions

Uganda's adoption of the CBD definitions of "genetic resources" emphasize a utilitarian interpretation that is at the discretion of the country. However, the fact that Section 4 only provides suggestions on Uganda's intended definition, creates significant potential for confusion. As the implementation of the regulations continues, the competent authority may find the need to issue an interpretative statement on this issue. In the meantime, it seems reasonable to suggest that Uganda's definition of genetic resources involves two elements:

1. Physical/natural – "genetic resources" includes all biological organisms and components thereof, including DNA and RNA, as well as derivative synthetics, combinatorial compounds, and raw and modified extracts.
2. Legal-political – "genetic resources" includes the reproducible (whether naturally or artificially) characteristics of a biological organism and not its immediate consumptive characteristics. In addition, the activities of local communities and research institutions¹⁰⁵ are exempted from regulation, as are activities involving material sourced from formally recognised plant breeders.

⁹⁸ Personal communication to Peter G. Munyi by Dr Charles Mugoya, Deputy Executive Secretary UNCST (16 March 2004).

⁹⁹ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

¹⁰⁰ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

¹⁰¹ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

¹⁰² This initiative is being undertaken with the support of the Genetic Resources Policy Initiative (GRPI) of the International Plant Genetic Resources Institute (IPGRI). See www.grpi.org.

¹⁰³ Personal communication to Peter G. Munyi by Dr Charles Mugoya, Deputy Executive Secretary UNCST (16 March 2004).

¹⁰⁴ Personal communication to Peter G. Munyi by Dr Beatrice Male-Kanyiswa, NARO Entebbe Botanical Gardens (15 March 2004).

¹⁰⁵ It is not clear to which research institutions this applies.

The legal status of genetic resources in Uganda

Uganda has not specifically addressed the question of the legal status of genetic resources in terms of ownership or outlined the legal basis of the State's right to regulate. The Statute and ABS regulations do not contain any provisions relating to this issue. The lead agencies¹⁰⁶ all operate on the understanding that ownership of genetic resources follows the tenure of the land on which they may be found.¹⁰⁷ Given that Uganda is a Common Law country, a legal framework supporting this understanding can be constructed with its legitimacy deriving from the Constitution of the Republic of Uganda (1995)¹⁰⁸ and orthodox common law interpretations of its relevant clauses. Lead agencies recognize ownership as following land tenure and distinctions between ownership and control. The government asserts general authority to regulate access to genetic resources regardless of their ownership status.¹⁰⁹ As is the case with ownership, a clear legal framework for these governmental rights can be defined, with its roots in the Constitution and statute.

Ownership of genetic resources

There is no specific reference to the ownership of genetic resources in any Ugandan law in force. However, given that genetic resources are an asset and property, a pattern of ownership can be traced. The concept of genetic resources as property is reinforced by Uganda's adoption of the CBD's approach to the definition of genetic resources based on socio-economic perceptions rather than natural properties.

Uganda is a common law country and thus rights to property are established in a manner similar to that of most countries implementing such a legal system.¹¹⁰ Common law principles are subject to constitutional and statutory law, but as noted, there is no specific reference to the ownership of genetic resources in Ugandan law. Common law recognizes two basic categories of property: "real" and "personal". Under common law, there is an intimate relationship between land and any resources found on, under or above it, such that the ownership of these resources normally follows that of the land.¹¹¹ Genetic resources may be a form of resource that has only recently been of any significance in the legal and political spheres, but they, or at a minimum terrestrial and freshwater marine resources, would appear to fit logically within the existing common law framework. Personal property basically includes everything that is the subject of ownership, but not included in the concept of real property. Within this concept there are two basic elements: tangible property includes

¹⁰⁶ NEMA, UNCST and NARO.

¹⁰⁷ Personal communications to Peter G. Munyi by Dr Beatrice Male-Kanyiwa, NARO Entebbe Botanical Gardens (15 March 2004), Robert Wabunoha, Senior Legal Counsel, NEMA (19 March 2004)] and Dr Julius Ecuru, Head of Scientific and Industrial Research and Development, UNCST (17 March 2004).

¹⁰⁸ The Ugandan Constitution. See: <http://www.government.go.ug/constitution/index.php>. Date accessed: October 2003.

¹⁰⁹ Personal communications to Peter G. Munyi by Dr Beatrice Male-Kanyiwa, NARO Entebbe Botanical Gardens (15 March 2004), and Dr Julius Ecuru, Head of Scientific and Industrial Research and Development, UNCST (17 March 2004).

¹¹⁰ Section 16 of the Judicature Statute (1996) provides the hierarchy of applicable law in Uganda: written law; common law and doctrines of equity; custom and usage; and, principles of natural justice, equity and good conscience. The constitution is superior to all of these and international treaties have the status of written law under Article 76 of the constitution and through the parliamentary process of ratification.

¹¹¹ Minerals and airspace are the most common statutory exceptions to this principle, while wildlife is often also subject to separate regulation in African jurisdictions.

movable and tangible things, such as money or goods; while intangible property includes things such as IPRs, stocks and shares.

In the absence of specific statutory provisions or precedents, it is difficult to be certain of the ownership of genetic resources in Uganda. Practice suggests that, at least in their terrestrial form, genetic resources are considered as part of rights in real property, as part of the “fruit of the land”. However, it should be borne in mind that, given that the primary value of a genetic resource often lies in intangible characteristics or traits (more particularly knowledge of these characteristics or traits), it is possible that they could be seen more as elements of personal property. It should also be noted that the relationship between real and personal property rights in genetic resources is extremely complex, particularly where issues such as IPRs are involved. On the one hand, one is dealing with a specific sample of a resource from a particular location and, on the other, one is most often dealing with an abstract value of a resource that is not necessarily particular to any given sample. If private rights are to be granted for personal property in genetic resources, the issue of who owns those rights has the potential to be extremely controversial.

Land tenure in Uganda is divided into five categories, consisting of public land and four forms of private land tenure recognized by Article 237(3) of Chapter 15 of the 1995 constitution:¹¹² customary, freehold, *mailo* and leasehold. Freehold and leasehold conform to the generally accepted common law understanding of those terms, while *mailo* and customary tenure are more specific to the situation of Uganda.

Under freehold tenure, the question of ownership depends on the discussion of common law interpretations discussed earlier, as the owner has unfettered rights to their land and to resources associated with it. As discussed earlier, this is subject to constitutional and statutory provisions and thus does not imply unfettered rights to control. This is a relatively simple picture, however, and it should be noted that were genetic resources to be interpreted as subject to personal property rights, the situation would change sharply. Emphasis would be on the nature and characteristics of a genetic resource in general, rather than on rights to a particular sample of a resource found in a particular location. Under leasehold tenure, the ownership of resources largely depends on the nature of the lease. The majority of long-term leases provide that resources associated with land are, except where explicitly stated to the contrary, “part of the package”. Given that genetic resources are rarely, if ever, specifically addressed in a lease, this will usually be the case. Similar to the situation with freehold tenure, a lease will be subject to any constitutional or statutory restrictions on rights.

*Mailo*¹¹³ land is, in some respects, a modern form of customary land tenure resulting from the Buganda Agreement (1900) between the British colonial authorities and the Kingdom of Buganda. Hence, it only applies in the Kingdom of Buganda, which occupies a large part of central Uganda, including the capital, Kampala. *Mailo* is essentially a feudal system with land owned in perpetuity by individual land owning families and the Kabaka’s (King’s) Government and thus only *mailo* owners can acquire titles to land in these areas. However, the majority of the occupants of *mailo* land are tenants. From 1928 onwards, tenants’ (including new entrants where such entry is with the consent of the landlord) rights to tenure and usage have been protected subject to the payment of taxes. Eviction could only be effected subject to compensation. The fact that genetic resources are rarely considered in land transactions again plays a significant role here. Under the *mailo* system, the rights to genetic resources found on a piece of land are likely to transfer as part of the land and thus the lessee will probably be found to have the power to exercise rights on behalf of the *mailo* owner.

¹¹² The Ugandan Constitution. See <http://www.government.go.ug/constitution/index.php>.

¹¹³ The term *mailo* is derived from the Luganda word for miles, as the original grants of tenure under the Buganda Agreement were measured in square miles.

This is reinforced by the semi-permanent nature of mailo leases that require compensation for eviction. However, a more thorough study of precedents involving natural resources found on mailo land might be warranted to provide some limited measure of certainty.¹¹⁴

The situation with land held under customary tenure is potentially the most complex as regards the ownership of genetic resources. It is impossible to provide any form of genuinely comprehensive picture, as customary tenure is, *per se*, dependant on the particular area or ethnic group in question. However, some basic common points may be noted. First, there is normally a basic division in practice between sedentary and nomadic – or more accurately, transhumant – groups. Sedentary groups often come closer to western concepts of private rights than transhumant groups. However, these “private rights” are usually still subject to some form of collective review, such as through councils of elders. This suggests that the underlying right is not really one of ownership, but one of user rights granted to an individual (whether alone or in perpetuity, including heirs and assigns). The concept of user rights appears to be the dominant concept among transhumant groups, where individuals, families or clans, subject to community acceptance of such claims, may control rights. In these situations, the underlying ownership right lies with the community as a collective and is often inalienable. The means by which a given community may take a decision or express its view may, or may not, be iterated in law depending on the exact status of a particular piece of land.¹¹⁵ Detailed information on resource rights and ownership under customary tenure systems is often available in anthropological literature but, to date, there has only been a limited crossover of this information into the legal and policy fields.

In conclusion, it can be said that the ownership of genetic resources in Uganda is not a straightforward issue, but varies according to the land tenure system applicable to the land where a given resource is found. In accordance with the common law, genetic resources could also be interpreted as personal property, but there are no precedents or indications to this effect. The question of how personal property rights might be asserted would require some specific measures in law.

Access to and control of genetic resources

Ownership of genetic resources may be an important question, but control over genetic resources is more significant in the context of ABS provisions. The reason for this situation is illustrated by the case of Uganda, where ownership of genetic resources is not explicitly addressed in law, but control is. Ownership is therefore rendered moot in the context of access to genetic resources regulation, as it is the rights of control that determine the ABS framework.

Rights of control over genetic resources operate on three distinct legal levels according to the Ugandan Constitution. Articles XI, XIII and XXVII of the Constitution’s National Objectives and Directives of State Policy provide broad authority to the state that is relevant to genetic resources. Article XI(iii) provides that “the state may regulate the ownership, use and disposition of land and other property”. This is limited by a requirement that such regulation be in accordance with the constitution. It, however, clearly encompasses genetic resources, whether their legal status is as part of real or personal property. Articles XIII and XXVII(iv) focus more on the sustainable management of natural resources, with the former requiring the state to protect resources, “including land, water, wetlands, minerals, oil, fauna and flora on behalf of the people of Uganda” and the latter requiring the state to “promote ...

¹¹⁴ Limited time and funding has precluded the conducting of even a preliminary examination of detailed questions such as this for this study to date.

¹¹⁵ Trust land or its equivalent, for example, in a number of African states usually has some decision-making process associated with it, often involving local government authorities.

rational use ... to safeguard and protect the biodiversity of Uganda.” Again, these provisions can logically be seen to provide broad discretion to the state to regulate access to genetic resources as it deems necessary, with only limited provisos relating to sustainable use and the general welfare of the people of Uganda.

The National Environment Statute builds on the powers granted to the state by the constitution and provides for a wide range of environmentally related issues. The statute does not directly refer to the constitutional provisions that are the basis of the state’s power to regulate.¹¹⁶ This is because the statute was drafted prior to the final adoption of the current constitution and not due to the concern over the validity of the regulatory powers asserted. Article 45 of the statute specifically addresses the regulation of access to genetic resources in Uganda:

“The authority shall, in consultation with the lead agency, issue guidelines and prescribe measures for the sustainable management and utilization of genetic resources of Uganda for the benefit of the people of Uganda.

Without prejudice to general effect of Subsection 1, the guidelines and measures issued or prescribed under that Subsection shall specify:

- a. appropriate arrangements for access to the genetic resources of Uganda, by non-citizens of Uganda including the fees to be paid for that access;
- b. measures for regulating the export of germplasm;
- c. the sharing of benefits derived from genetic resources originating from Uganda; and
- d. any other matter which the authority considers necessary for the better management of the genetic resources of Uganda.”

This Article, in particular paragraph 45.1 and subparagraph 45.2(d), provides very broad authority for the promulgation of regulations. Paragraph 45.2(a) places an emphasis on measures providing for the activities of non-citizens. The broad application of the other provisions means that this emphasis is not at the expense of measures regulating the activities of citizens or designed to be all embracing. Given the equally broad nature of the constitutional provisions mentioned earlier, it is likely that Article 45 would survive any constitutional challenge.

Uganda’s ABS regulations have been drafted pursuant to Article 45 of the statute and thus, by extension, pursuant to the broad regulatory powers provided to the state by the Constitution. These regulations are not yet in force, pending their adoption by the cabinet. It should, however, be noted that this does not mean that the fact that they are currently being implemented is without any legal mandate. The promulgation of regulations falls under “prescribed measures” in the statutory language, but this is without prejudice to the authority’s general powers of regulation. The current *de facto* implementation could thus be explained either as an exercise of general regulatory authority pending the prescription of measures or as the “issuance of guidelines”,¹¹⁷ thereby giving it the colour of law.

The third, and final legal level relating to the access to and control of genetic resources is the ABS regulations themselves. In Article 9, they unambiguously provide the detail that is absent from the constitution and the statute:

¹¹⁶ Section 44 of the Land Act (Act No. 16, 1998) provides such an explicit link in that it is the implementing legislation of the constitutional provisions on land tenure. It provides that “a person who owns or occupies land shall manage and utilize the land in accordance with the Forest Act, the Mining Act, the National Environment Statute, 1995, the Water Statute, 1995, the Uganda Wildlife Statute, 1996, and any other law”.

¹¹⁷ These would not require cabinet approval.

“The right to determine, control and regulate access to genetic resources and their derivative products or intangible components, whether, including biological resources of migratory species which by natural circumstances are found within Uganda, is vested in the government for the benefit of the people and shall be exercised in accordance with these regulations.”

It is unusual for such language relating to the assertion of authority to appear in the text of regulations rather than a parent statute. There is a possibility that it could be challenged on the basis of exceeding the statutory mandate for the regulations, but, again due to the broad nature of the statutory language, such a challenge would be difficult to sustain.¹¹⁸

In summary, the Uganda Constitution, Statute and ABS Regulations do not address the ownership of genetic resources in any specific manner. However, this point is moot as they clearly establish the right of the state to regulate access to and control over genetic resources. The state has unequivocally asserted this right in the ABS regulations.

Structure and process for access to genetic resources in Uganda

A range of provisions in the ABS regulations establishes the method of application and process of consideration for access to genetic resources in Uganda. There is no discrimination on the basis of the nature or identity of applicants (although Ugandan students receive concessionary fees), or regarding the location or source of genetic resources. In addition to the provisions explicitly established by the ABS regulations, the Competent Authority implements relatively strict limits on the time it allows for lead agency responses, pursuant to its mandate to facilitate the “expeditious processing of applications”. Analysis of the ABS regulations produces the following procedure:¹¹⁹

1. The application is submitted to Competent Authority (designated as UNCST) in Article 5, accompanied by an administrative fee and, in pursuant to the first schedule, contains the following information:
 - title of project;
 - main objective for access;
 - brief outline of access methodology;
 - geographic location of intended access;
 - estimated cost and source of funds; and
 - duration of access.
2. Competent Authority considers application and forwards to relevant lead agencies for their opinion (Art. 10.3). This is subject to Competent Authority’s obligations to expeditiously process applications (Art. 6.2(1)) and to coordinate the activities of lead agencies (Art. 6.2(2)).
3. Lead agencies review and advise Competent Authority in writing as to whether application should be granted or not (Art. 7.2(a)), opinions that are binding on the Competent Authority (Art. 19.1).
4. If the application is approved, the Competent Authority grants PIC, which allows an applicant to proceed further, but does not authorise any access activity (Art. 10.4). The Competent Authority will advise as to any accessory agreements that may be required pursuant to Article 11 (if the genetic resource in question is found on land owned or

¹¹⁸ It could possibly also be argued that by asserting these specific powers in the regulations, the executive is usurping the authority of the legislature, which did not grant these powers in the Statute. However, this argument also rests on the assertion that the statutory language could not be interpreted to include such powers and thus probably would not stand.

¹¹⁹ Pursuant to Article 27, transshipment of genetic resources does not need to go through this process, but instead requires a declaration and evidence of the legal acquisition of the genetic resources being transferred from their point of origin.

- controlled by a lead agency, private owner or community).¹²⁰ If the application is rejected, Competent Authority may advise on its shortcomings and accept resubmission.
5. If required under step 4, negotiation of accessory agreements are facilitated by the Competent Authority (Art 6.2(10)). Lead agencies to ensure rights of local communities are protected (Article 7.2(c)) and that all necessary accessory agreements are concluded (Article 7.2(d)).
 6. Negotiation of an MTA with Competent Authority (Art 10.5). Requirements for an MTA:
 - d) provide for depositing of duplicate samples ((Art 6.2(6) and (7), and 19.2(c)).
 - a) include benefit-sharing provisions satisfactory to the Competent Authority (Art 6.2(8) and (9)).
 - b) accompanied by prescribed administrative fee (Art 10.6).
 - c) incorporate accessory agreements by reference (Art 18).
 - d) include the following obligations for the collector (Art 19.2):
 - detailing of genetic resources (19.2(a)).
 - informing Competent Authority and other concerned parties of research results (19.2(b)).
 - respecting customs, traditions, values and customary practices of local communities (19.2(d)).
 - authorizing of third party transfer (19.2(e)) and applications for IPRs (19.2(f)).
 - paying of all fees (19.2(g)).
 - sharing of benefits arising from any IPRs (19.2(h)).
 - involving of Uganda citizens (19.2(i)).
 - submitting of regular status reports (19.2(j)).
 - e) include guidelines (non-binding as may vary on a case by case basis for benefit-sharing provisions) in Article 22.
 7. Upon the conclusion of an MTA the Competent Authority may issue an Access Permit (Art 10.5) to access or collect and export specified resources.
 8. The export of genetic resources requires the submission of additional information, the content of which currently is unclear.
 9. Subsequent to access to genetic resources any new use for a given resource, i.e. other than that specified in the original accessory agreements and MTA, will require new agreements and authorization from the Competent Authority and other interested parties under step 5.

Access requests and decisions

The regulation of access to genetic resources in Uganda has developed in three distinct phases. The first phase was pre-1997, when there was no active regulation and access was available without administrative procedures or monitoring. The second phase was from 1997 to 2002 and can be described as an interim period of ad hoc regulation. Records of access to genetic resources activity in these first two phases are minimal, with the best consisting of the activities of agricultural research institutions in sourcing germplasm from outside Uganda. It might be possible to piece together a more accurate, or at least indicative, picture of access from both Uganda and outside. This would entail a thorough examination of records at public institutions, such as Makerere University, research institutions, UNCST

¹²⁰ This link to land owners or occupiers reinforces the concept that the ownership of genetic resources is an element of rights in real property.

and, perhaps most importantly, the phytosanitary authorities; the cost-benefit justification for such time-consuming research is questionable.¹²¹

The third phase began in 2002, with the finalization of the draft ABS regulations, and represents the introduction of more formal and structured regulation. This third phase technically divides into the 2002–2004 period, in which the regulations were applied administratively, and the post-2004 period, in which the regulations have been in force. This distinction has not been maintained here for two reasons. One, at the time of writing there has been too little experience of the post-2004 situation to viably comment. Two, with one exception, the practical differences between the two periods of this third phase have been minimal. Before UNCST started to actively use the draft regulations, there was a national workshop, in May 2001, where a broad range of stakeholders were involved. This workshop reached a “consensus on interim measures for transfer or export of genetic material from Uganda for research purposes” and the application of the draft regulations on the basis of this consensus was never challenged, notwithstanding that they did not have the force of law.¹²² As part of this administrative application, UNCST did not refer to the draft regulations in its authorization of requests for access and issued the clearance letters it has always issued for research, as opposed to the certificates provided for in the regulations, upon approval.¹²³ In effect, it co-opted the principles of the draft regulations into its existing research approval process. The one area where one might expect significant differences between the 2002–2004 and post-2004 periods is that of requests involving commercialization. In the administrative period, UNCST did not implement the provisions of the draft regulations on commercialization,¹²⁴ as mentioned in the discussion of the nature of access activities below, mostly because of concerns regarding legal force. Only more experience of the post-2004 period will show if this significantly affects the dynamics of the regulatory system.

Records have been routinely maintained during the post-2002 period due to the formalization of UNCST’s role as a coordinating and monitoring agency. The precise details of access requests and permissions are not presented here, but it is understood that UNCST is thoroughly analyzing its records to assess the effectiveness of recent regulatory and policy developments, and future policy development.

Access to genetic resources prior to 2002

As mentioned earlier, prior to 1997 there was no regulation of access to genetic resources, and consequently no centrally or formally managed records of access in Uganda. This was common to a large number of countries that still *de facto* operated on a concept of common heritage and free access, four years after the CBD in 1993, but 1997 was a watershed year for access to genetic resources in Uganda, due to events rather than any particular policy initiative. The key catalyst for change in the regulatory regime was revelations regarding the activities of a USA university in collaboration with a number of Ugandan academics. The basis of the programme was a pattern that has been repeated in a number of other countries.

¹²¹ Records of the 1997 to 2002 phase are probably more easily collated than earlier records due to the increasing role of UNCST as a coordinating and monitoring agency for access to genetic resources during this period. However, even this activity would require considerable effort in sifting through the general records of research requests and permissions.

¹²² Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

¹²³ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

¹²⁴ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

A group of Ugandan university lecturers were contracted by the USA university to collect and refine samples of medicinal plants used by local communities in Uganda. Refined samples, accompanied by information regarding the collection of the material and any known or suspected activity, were then shipped to the USA for a fee of US\$ 50 per sample. There is no accurate information regarding the number and nature of samples delivered to the USA under this programme, but it is suspected that hundreds of samples were involved.

In 1997, NEMA had yet to be fully established, with its parent statute only having been enacted in 1995. As a result, the Ugandan Government's reaction to the perceived problems of unregulated access to genetic resources was to mandate UNCST to regulate the field as an extension of its existing activities in regulating research in the country. This was initially undertaken within the existing framework of the granting of research permits. This required the submission of research proposals, but had little or no provision for benefit-sharing mechanisms, adequate guarantees or any of the other issues that have emerged as central to the regulation of access to genetic resources. In cooperation with lead agencies, UNCST adapted the existing framework to the degree it was able, but in partnership with NEMA and in consultation with stakeholders, it also led a dialogue to develop a regulatory system specific to access to genetic resources. This dialogue, which formally began in 1999, produced a complete draft in 2002 and, ultimately, led to the preparation of the ABS regulations. From 2002 until their entry into force in 2004, the ABS regulations were applied as the *de facto* access to genetic resources regulatory regime, pending their formal entry into force.

Access to genetic resources post-2002

As mentioned in the previous section, access to genetic resources in Uganda has been regulated as a specific field since 2002. This specific regulation has facilitated more efficient collation of information regarding the volume and nature of requests for access to genetic resources, although these are still considered within the context of broader requests for research permits. UNCST currently estimates that it has received an average of twenty research requests per calendar month from 2002 to date.¹²⁵ Of these, it estimates that about one-quarter involve questions of access to genetic resources.¹²⁶ The overwhelming majority of all research applications, >95%, received by UNCST are from local and foreign university-based researchers.¹²⁷ It is not entirely certain to what degree the system is capturing information on some domestic activities as it is, at a minimum, clear that national research institutions exchange material fairly freely among themselves without always following regulatory requirements.¹²⁸ Of the applications received from foreign researchers, almost all

¹²⁵ Personal communication to Peter G. Munyi by Dr Charles Mugoya, Deputy Executive Secretary UNCST (16 March 2004).

¹²⁶ Personal communication to Peter G. Munyi by Dr Charles Mugoya, Deputy Executive Secretary UNCST (16 March 2004) and by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (19 March 2004).

¹²⁷ Personal communication to Peter G. Munyi by Dr Charles Mugoya, Deputy Executive Secretary UNCST (16 March 2004).

¹²⁸ Personal communication to Peter G. Munyi by Dr Beatrice Male-Kanyiwa, NARO Entebbe Botanical Gardens (15 March 2004). To a certain degree, this is to be expected, as the motivation for the development of the regulations, which continues to be a prime concern, was irregular foreign access to Ugandan material rather than domestically conducted research. However, it remains to be seen whether domestic activities will increasingly be brought within the scope of the regulations as a function of the relationships between Ugandan researchers and local communities or landowners.

involve some form of access to genetic resources and require an MTA.¹²⁹ The general fields of research in which applications fall are monitored, and the majority of applications requiring access to genetic resources authorization fall within the fields of agriculture, biomedical and natural sciences research.¹³⁰ Despite this relatively significant level of activity, there is, as yet, only very limited experience with requests focusing on commercialization.¹³¹ This is partly because very few have been received and partly because, where they have been received, UNCST has limited its approval to the research elements of the request.¹³² The reason for this approach appears to be connected with a desire to wait for the entry into force of the regulations¹³³ and to gain greater understanding of the dynamics of commercial requests, both largely being questions of confidence building within the Ugandan authorities.

¹²⁹ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (19 March 2004).

¹³⁰ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (19 March 2004). While these very broad categorizations do not provide any great detail regarding the precise nature of activities (although UNCST does maintain greater detail), they do at least suggest that there is not a particular concentration of activity in one area of the life sciences.

¹³¹ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

¹³² Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

¹³³ Personal communication to Peter G. Munyi by Dr Julius Ecuru, Head of Scientific and Industrial Research and Development UNCST (17 March 2004).

